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This annual report summarizes work performed during the first year of a three-year study to evaluate full-field digital mammography (FFDM) as a screening tool for breast cancer. The first year's work on this project was devoted to acquisition and technical evaluation of two prototype full-field digital mammography systems (GE Medical Systems, Inc.). In addition to complete acceptance testing of each FFDM unit, contrast-detail phantoms were used to evaluate and compare different FFDM image acquisition and display modes for the detection of low-contrast lesions. Contrast detail phantoms also were used to compare the performance of FFDM with that of screen-film mammography (SFM) for low-contrast lesion detection. Preliminary results of our clinical study comparing SFM to FFDM as screening tools for breast cancer, including women accrued between August and December 31, 1997, are also presented.

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R E Hendrick 2/3/98

PI - Signature Date

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INTRODUCTION

This report summarizes the work performed in year one of a three-year study to evaluate full-field digital mammography (FFDM) as a screening tool for breast cancer. The first year's work on this project was devoted to acquisition and technical evaluation of two prototype full-field digital mammography systems, comparison of low-contrast lesion detection using FFDM with that of screen-film mammography, and implementation of a clinical study comparing screen-film and FFDM in screening for breast cancer.

This project began on December 30, 1996. The first stages of the project were the development of software for recording and evaluating radiographic outcomes for screen-film and digital mammography, room renovation, and preparation for installation of two FFDM units, one at the University of Massachusetts Medical Center (UMMC) and another at the University of Colorado Health Sciences Center (UCHSC). The University of Massachusetts received the second prototype GE Medical Systems FFDM unit in March 1997; the University of Colorado Health Sciences Center received the third prototype FFDM unit in April 1997 (the first prototype GE-FFDM unit went to MGH approximately 6 months earlier). A complete acceptance test of each FFDM unit was conducted by board certified medical physicists, Dr. Andrew Karellas at the University of Massachusetts Medical Center (UMMC), Dr. R. Edward Hendrick at the University of Colorado Health Sciences Center (UCHSC). Copies of the acceptance test reports for each unit are contained in the Appendix as **Attachment A**. We are also in the process of developing a complete quality control (QC) program for FFDM. This program is for both radiologic technologists and medical physicists, and is being developed and tested in conjunction with GE Medical Systems, Inc. An outline of the QC program and data collection forms is included in the Appendix as **Attachment B.**

Institutional review board approval was received at each institution in April 1996. Training of radiologists in the use of the GE Advantage Workstation was done at the time of system delivery in March and April 1997. Additional training was done prior to the start of clinical imaging by Ms. Kathy Priday, GE Global Applications Specialist. Technologist training in use of the equipment was conducted in June 1997 at both sites by Ms. Kathy Priday. Clinical imaging under the IRB protocol began in August 1997. As of December 31,1997, 503 women had been imaged under this protocol at UCHSC, and 463 had been imaged under this protocol at UMMC.

The goal of this project is to evaluate FFDM as a screening tool for breast cancer. The project is designed to compare FFDM to screen-film mammography (SFM) in a large group of women being screened for breast cancer. Women seeking screening at UMMC or UCHSC are informed of the research project and

asked to consent to both SFM and FFDM of each breast. For women consenting to the study, cranio-caudal (CC) view and medio-lateral oblique (MLO) view FFDM images are acquired of each breast at the same technique factors and radiation doses as for SFM. Images from each modality are read independently by board certified, MQSA-qualified radiologists with the same information (patient history and prior mammograms when available) available for interpretation of each modality. Any discrepancies between outcome recommendations are resolved by two radiologists reviewing both the images and interpretations from FFDM and SFM simultaneously and jointly making a single recommendation for follow-up. In general, unless an explanation for a finding can be determined by looking at the other modality, findings seen on either modality are worked up. This process is designed to remove bias about follow-up of one modality over another. Interpretation results are entered on computer and maintained at each facility. Results have been merged between facilities and analyzed both separately and collectively in a preliminary analysis for this report.

BODY OF REPORT

The body of this report contains Methods and Results of the first year's progress in this project on full-field digital mammography. The Methods for all experiments are listed first, then the corresponding Results.

I. Methods

Optimization of Mammographic Technique Factors for FFDM

In addition to acceptance testing, a contrast-detail (CD) phantom of our own design (**Figure 1**) was used to quantitatively evaluate image quality over the full range of compressed breast thicknesses (2-8 cm) for average breast composition (50% fatty/50% glandular). First, different digital image receptor options were used with identical technique factors matched to the target-filter, kVp, and mAs obtained using screen-film mammography on the GE-DMR operating in AOP-Contrast mode for each breast thickness. The digital image receptor options considered were: 50 micron pixels without grid, 50 micron pixels with grid, 100 micron pixels without grid, 100 micron pixels with grid. The CD phantom consists of a 9 by 9 array of low-contrast circular test objects milled into a D-shaped 1 cm thick section of breast equivalent material, to which additional 1 cm thick sections of D-shaped breast materials were added to give the total thicknesses of 2, 4, 6, and 8 cm. Each row of the CD pattern contained 9 low-contrast targets at a fixed level of contrast (ranging from 0.29% to 3.95%). Each column had a different object diameter ranging from 0.25 mm to 4 mm (see **Figure 2**). FFDM phantom images were read using soft-copy display on the same GE Advantage Workstation used for interpretation of digital mammograms.

Three medical physicists trained in scoring the phantom under standardized viewing conditions independently evaluated CD phantom images. Reviewers read the phantom independently starting with the row of objects with highest contrast, and reading from largest to smallest detectable in that row. Once an object was too faint to "detect", counting was stopped and the number of consecutively visible objects for that row was totaled. Reviewers were instructed not to skip over an undetected object in a given row. They were also instructed to compare marginally detected objects to the background of the phantom and to not count objects that were no more visible than artifacts. Since the locations of the objects in the phantom were known in advance, this guarded against overscoring the phantom and provided greater consistency in scoring. The CD score for each reviewer under each imaging condition was determined by summing the area of detected objects in contrast-detail space (**Figure 3**). Thus, the more low-contrast objects of a given size and level of contrast detected, the higher the CD score. If all 81 objects in the CD phantom were detected, a maximum score of 17.34 would be obtained. If no objects in the CD phantom were detected, a minimum score of zero

would occur.

Comparison of FFDM to SFM: Low-contrast Lesion Detection

The same CD phantom described above was used for the comparison of FFDM and SFM. All SFM image acquisition was done on a GE-DMR mammography unit using automatic optimization of parameters (AOP) mode. Kodak Min R-2000 film was used with a set of three Kodak Min R- 2000 cassettes matched for optical densities. Films were processed on a Kodak M8 processor with Kodak chemistry and autoloading. SFM phantom images were obtained with a narrow range of background film optical densities yielding maximum low-contrast detection (1.60-1.70). SFM was performed first and technique factors were recorded for each breast thickness (2, 4, 6, and 8 cm) and composition (100% fatty, 70% fatty/30% glandular, 50% fatty/50% glandular, 30% fatty/70% glandular, and 100% glandular except for 1 cm of fat-equivalent tissue). Based on the SFM techniques, identical target-filter and kVp settings were used for each simulated breast thickness and composition when FFDM was performed. When available on FFDM, the same mAs setting was used. When an exact match was unavailable, the next lower mAs setting was used for FFDM as had been used for SFM.

SFM images were independently read by the same three medical physicist readers who scored FFDM images. SFM was read using standardized viewing conditions, as were FFDM images. Readers were aware of the modality, but were blinded to the particular exposure conditions of each image. As above, results were quantitated in terms of CD scores: the area of detected objects in contrast-detail space (see **Figure 3**).

Preliminary Analysis of Clinical Study Data

The study population for the clinical comparison of FFDM and SFM is defined as all women who enter a participating facility (UCHSC or UMMC) for 2-view mammography of both breasts. Women excluded from the study include women under the age of 40 years, women with breast implants, and women with breasts too large to be adequately positioned on the 24x30 cm screen-film image receptor. All qualifying women entering mammography at each participating facility are asked to participate in the study and are informed of the study design and potential risks. Those women who meet entry criteria, who are willing to sign an informed consent form, and who successfully undergo both SFM and FFDM of both breasts at the study site are included in the study population.

Women participating in the study are examined by screen-film mammography using phototimed techniques (AOP Contrast Mode) prior to examination by FFDM. Technique factors (target material, filtration material, kVp, and mAs), compression force, and compressed breast thickness are recorded for each view of each breast in screen-film mammography. FFDM is then be

performed using technique factors that produce equal or slightly lower average glandular breast doses for each view of each breast. Technique factors for FFDM, including compression force and compressed breast thickness, are also recorded for each view of each breast. All FFDM image acquisitions employ a grid (as do all screen-film images) and 100 micron pixel sizes.

For each case, screen-film and digital mammograms are independently interpreted by different MQSA-qualified interpreting physicians. Each interpreting physician has the same prior knowledge of the case, which includes a patient history form and any prior mammograms available for the woman. Interpreting physicians read an approximately equal number of screen-film mammograms and digital mammograms.

ACR BIRADS categories are used to assess findings for each modality. These ACR BIRADS categories are:

ACR BIRADS Category	Finding
0	Additional evaluation needed
1	Normal
2	Abnormal - benign
3	Abnormal - probably benign
4	Suspicious for cancer
5	Highly suspicious for cancer

Digital mammograms are interpreted using soft-copy display on a GE-FFDM Advantage Workstation with two high resolution, high luminance monitors, a SUN UltraSPARC computer. This is done to take advantage of the ability to manipulate digital data in a manner that permits visualization of the entire breast or enhanced visualization of possible suspicious findings within a region of the breast.

A preliminary analysis of the women screened between the start of the clinical study (August 1997) and December 31, 1997 was performed. This provided both an evaluation of our patient database storage and retrieval software and a preliminary evaluation of the clinical study. Independent radiologist readings of FFDM and SFM were analyzed. In cases where there was a discrepancy between SFM and FFDM, the discrepancies were also analyzed.

Results were based on the evaluating radiologist's follow-up recommendations. Radiologist's results in ACR BIRADS categories 0 (needs further diagnostic evaluation), 4 (suspicious for malignancy), and 5 (highly suspicious for malignancy) were considered positive. Radiologist's results in ACR categories 1 (normal), 2 (benign), or 3 (probably benign) were considered negative. Agreement between FFDM and SFM was assessed in a two-by-two table of positive and negative outcomes, as shown below:

		Screen-film Assessment +	-	
				Digital Totals
Digital	**+**	**a**	**b**	ND+ = **a + b**
Assessment	**-**	**c**	**d**	ND- = **c + d**
Screen-Film Totals		NSF+ = **a + c**	NSF- = **b + d**	

Truth about positivity and negativity of breast cancer, and therefore truth about digital and SF assessment is established through follow-up data. Relatively immediate follow-up results are available for cases that are SFM positive, FFDM positive, or both (categories **a, b**, or **c** in the chart above). The truth about cases assessed to be negative by both modalities is determined only by long-term follow-up and by linkage with cancer registries in Colorado and Massachusetts to determine false negative results. A more detailed analysis is presented on cases where disagreement exists between FFDM and SFM (categories **a** and **b** above). Analyses are presented collectively and separately for the two institutions (UCHSC and UMMC) to assess possible differences in clinical practice or assessment thresholds.

II. Results

Optimization of Mammographic Technique Factors for FFDM

Optimization studies to date have evaluated the performance of different detector resolution and grid combinations with identical technique factors. Technique factors for different breast thicknesses were matched to the target-filter, kVp, and mAs obtained using screen-film mammography on the GE-DMR operating in AOP-Contrast Mode. Detector resolution and grid options studied included: 50 micron pixels without grid, 50 micron pixels with grid, 100 micron pixels without grid, and 100 micron pixels with grid. **Figure 4** summarizes contrast-detail (CD) results of these digital image acquisition modes for 2-8 cm thick compressed breasts. Error bars on each data point represent one standard deviation in CD scores determined from three independent readers scoring each image. T-tests for statistical significance of differences revealed marginally higher scores using 100 micron pixels without grid for 2 cm thick breasts, no differences among acquisition modes for 4 cm thick breasts, and marginally significantly higher CD scores using 100 micron pixels with grid for 6 and 8 cm thick breasts. These

results indicate that best results would be obtained using 100 micron acquisition mode for all breasts, without grid for compressed breasts under 5 cm and with grid for compressed breasts thicker than 5 cm. Unfortunately, the grid is not removed or replaced in a simple fashion on the current GE-FFDM prototype system. Changing grid use requires a service person or medical physicist to remove the image receptor assembly cover by removing external attachment screws, attaching or detaching the grid using a set of attachment screws, and replacing the assembly cover with additional attachment screws. As a result of this CD phantom testing and the equipment constraint mentioned above, we have opted to use 100-micron pixels with grid exclusively for our clinical protocol. This yields improved low-contrast lesion detection for thicker breasts (average compressed breast thickness at UCHSC was determined to be 5.5 cm), while incurring substantially the same image quality as 100 micron non-grid techniques for thin to average breasts. These results were presented in a scientific paper presented at the 1997 Annual Meeting of the Radiological Society of North America.

Comparison of FFDM to SFM: Low-contrast Lesion Detection

Comparison of FFDM to SFM was done using the same CD phantom described above. Technique factors were determined to be those chosen by the GE-DMR in AOP Contrast Mode. AEC set-up dictated that these techniques maintained constant optical densities between 1.60 and 1.70. These optical densities were found to maximize CD scores in a series of independent experiments using the same screen-film combination. FFDM technique factors were matched identically to the target-filter and kVp settings used in screen-film mammography. mAs values selected for FFDM were identical to those selected for SFM when possible; when a particular mAs used in screen-film was unavailable for FFDM, the next lowest mAs was selected manually for FFDM. This ensured that the radiation dose for FFDM was equal to or slightly less than that for SFM.

CD scores for SFM and FFDM with a grid for breast thicknesses ranging from 2-8 cm are shown in **Figures 5-7**, each figure for a different breast composition. Analyzed collectively, these data show a statistically significantly higher CD score for FFDM than for SFM ($p<0.01$). Comparison of CD scores using SFM and FFDM without a grid is shown in **Figure 8**. It should be noted, however, that the dose was reduced to approximately half in the case of SFM to yield optical densities in the optimum 1.60-1.70 range. These results showed FFDM to have significantly better low contrast lesion detection than SFM ($p < 0.05$). These results were also presented in a scientific paper presented at the 1997 Annual Meeting of the Radiological Society of North America.

Preliminary Analysis of Clinical Study Data

From August through December 31, 1997, both sites combined have examined 966 women (503 at UCHSC and 463 at UMMC). Of these 966 women,

21 are awaiting completion of follow-up; 945 women were read as negative in both exams or have completed follow-up for positive assessment by one or both modalities. At entry, 923 of these 945 were asymptomatic, 22 were symptomatic. The following two-by-two table of outcomes compares the independent assessment of FFDM and SFM (by different interpreting physicians) in these 945 women:

		Screen-film Assessment		
		+	**-**	**Digital Totals**
Digital	**+**	**61**	**66**	ND+ = **127**
Assessment	**-**	**106**	**712**	ND- = **818**
Screen-Film Totals		NSF+ = **167**	NSF- = **778**	

Of the 61 cases interpreted as positive using both SFM and FFDM, 2 were true positives and 59 were false positives. Of the 66 cases interpreted as positive using FFDM, but negative using SFM, all 66 were found to be negative at follow-up. Of the 106 cases interpreted as positive by SFM, but negative by FFDM, 104 were found to be negative and 2 were found to be positive at follow-up.

After independent readings by different radiologists, all discrepancies between screen-film and digital mammography interpretations were resolved by discrepancy evaluations, with completion of a discrepancy form. In the case of the two cancers detected by SFM and missed by FFDM, both were detected based on calcifications. In one case, the calcifications were more visible on SFM than FFDM due to superposition of other tissues on the FFDM and not on SFM. In the other case, in retrospect the lesion was more visible on FFDM that SFM, but a detection error occurred in evaluation of FFDM. This suggests that there may have been a problem with the method of image review being used in soft-copy evaluation of the FFDM.

Recasting these preliminary data in terms of 2 by 2 truth tables separately for SFM and FFDM yields the following results.

SFM Results:

	Truth (pending additional follow-up) +	-	Screen-Film Totals
Screen-Film Assessment +	**4**	**163**	NSF+ = **167**
-	**0**	**778**	NSF- = **778**
Totals	**4**	**941**	**945 cases**

FFDM Results:

	Truth (pending additional follow-up) +	-	Digital Totals
Digital Assessment +	**2**	**125**	ND+ = **127**
-	**2**	**816**	ND- = **818**
Totals	**4**	**941**	**945 cases**

These results translate to the following comparative statistics between FFDM and SFM:

Effectiveness Parameter	**Results SFM**	**FFDM**
Sensitivity	100%	50%
Specificity	83%	87%
PPV	2%	2%
NPV	100%	100%

It should be noted that the number of cases, and in particular the number of cancers, is too small at this point to draw statistically valid conclusions from these results. In addition, sufficient time must elapse to have the opportunity to accrue false negatives, which will tend to lower both sensitivity and NPV for each modality.

A major concern about FFDM is the concern that it may generate an excessive number of false positive mammograms. This concern does not appear to supported by the preliminary statistics cited above, which show 163 false positive interpretations by SFM, 125 by FFDM. These preliminary results indicate the potential of this study to discriminate between the performance of SFM and FFDM in an essentially screening population. **Table 1** includes additional details of the clinical results accumulated collectively and at UCHSC and Ummc individually as of December 31, 1997.

It has been noted that accrual of examinees for the first six months of this project has not been at the level estimated in our proposal. This has been due to the delay in beginning the clinical protocol which was in part due to a 3-4 month delay in installation of the two prototype GE FFDM units. These delays resulted from detector production delays and room renovation delays. Additionally, we have not been able to accrue patients at the rates estimated in our proposal due to the time required to learn to use the FFDM system efficiently, the additional time required to perform SFM and FFDM and complete all required paperwork for the protocol, and due to cancellations and no-show examinees. The project Executive Committee (Dr. Hendrick, Dr. Lewin, Ms. Vance, and Dr. D'Orsi via telephone) held a day-long meeting in early January concerning these issues and developed a number of measures that are now being taken to increase the numbers of examinees participating in the protocol. These include altering the daily schedule to open up more digital mammography slots at each site, including information about the digital mammography project in patient reminder letters and mentioning it in reminder telephone calls. Staffing is being increased at UCHSC to support these additional activities and we are attempting to get similar staffing increases at ummc. Throughput of examinees will be monitored carefully on a month-by-month basis to evaluate the effect of these changes on the number of examinees at each site. We have also had preliminary discussions with two other sites where prototype GE-FFDM units have recently been installed (University of Pennsylvania and University of Chicago) to explore the possibility of extending this protocol to those sites. Additional funding will have to be sought and obtained to ensure their participation.

CONCLUSIONS

Our technical evaluation results indicate that the imaging parameters that maximize low contrast lesion detection for FFDM are 100 micron pixels without grid for thin compressed breasts and 100 micron pixels with grid for thicker compressed breasts. No difference was observed for intermediate breast thicknesses. FFDM with 100 micron pixels was superior to SFM in the detection of low contrast lesions when compared over a wide range of breast thicknesses and compositions using identical technique factors ($p<0.01$). 966 women received both FFDM and SFM under this protocol from August 1997 to December 31, 1997. Preliminary data have been analyzed on the 945 women with complete follow-up as of January 31, 1998. Preliminary results to date indicate that FFDM has fewer false positives than SFM, but also has lower sensitivity to breast cancer than SFM. These preliminary lack statistical power due to the few breast cancer cases included in the study protocol to date.

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APPENDIX

TABLE 1

FFDM-SFM COMPARISON STUDY
DATA SUMMARY
1/31/98

Both Sites Combined
Total exams performed through 12/31/97: 966
(945 have been entered into database as of 1/31/98 - 21 are awaiting completion of workup of findings)

Screening (asymptomatic): 923
Diagnostic (symptomatic or annual follow-up of lumpectomy or probably benign lesion): 22

Negative/Benign on both modalities (BIRADS 1 or 2): 712
Additional Evaluation Required, Probably Benign or Biopsy on at least one modality (BIRADS 0,3,4 or 5): 233

Exams with **agreement** between Film and Digital:
- Negative/Benign (truth to be assessed by long-term surveillance): 712
- False Positive: 59
- True Positive: 2

Exams with **disagreement** between Film and Digital:
- False Positive on Digital / True Negative on Film: 66
- False Positive on Film / True Negative on Digital: 104
- True Positive on Digital / False Negative on Film: 0
- True Positive on Film/ False Negative on Digital: 2

University of Colorado Only
Total exams performed through 12/31/97: 503
(498 have been entered into database as of 1/31/98 - 5 are awaiting completion of workup of findings)

Screening (asymptomatic): 483
Diagnostic (symptomatic or annual follow-up of lumpectomy or probably benign lesion): 15

Negative/Benign on both modalities (BIRADS 1 or 2): 367
Additional Evaluation Required, Probably Benign or Biopsy on at least one modality (BIRADS 0,3,4 or 5): 131

Exams with **agreement** between Film and Digital:
- Negative/Benign (truth to be assessed by long-term surveillance): 367
- False Positive: 35
- True Positive: 1

Exams with **disagreement** between Film and Digital:
- False Positive on Digital / True Negative on Film: 28
- False Positive on Film / True Negative on Digital: 66
- True Positive on Digital / False Negative on Film: 0
- True Positive on Film/ False Negative on Digital: 1

University of Massachusetts Only

Total exams performed through 12/31/97: 463

(447 have been entered into database as of 1/31/98 – 16 are awaiting completion of workup of findings)

Screening (asymptomatic): 440

Diagnostic (symptomatic or annual follow-up of lumpectomy or probably benign lesion): 7

Negative/Benign on both modalities (BIRADS 1 or 2): 345

Additional Evaluation Required, Probably Benign or Biopsy on at least one modality (BIRADS 0,3,4 or 5): 102

Exams with **agreement** between Film and Digital:

- Negative/Benign (truth to be assessed by long-term surveillance): 345
- False Positive: 24
- True Positive: 1

Exams with **disagreement** between Film and Digital:

- False Positive on Digital / True Negative on Film: 38
- False Positive on Film / True Negative on Digital: 38
- True Positive on Digital / False Negative on Film: 0
- True Positive on Film/ False Negative on Digital: 1

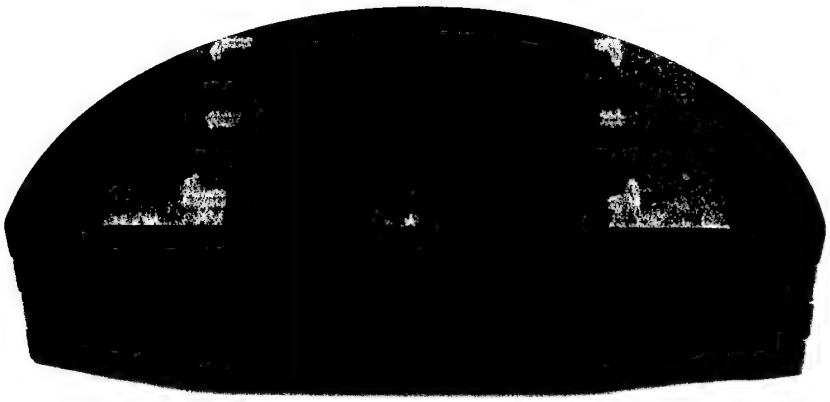


Figure1: The contrast-detail (CD) phantom developed and used in these experiments. The same 1 cm thick CD test pattern was used with different compositions and thicknesses of breast-equivalent materials.

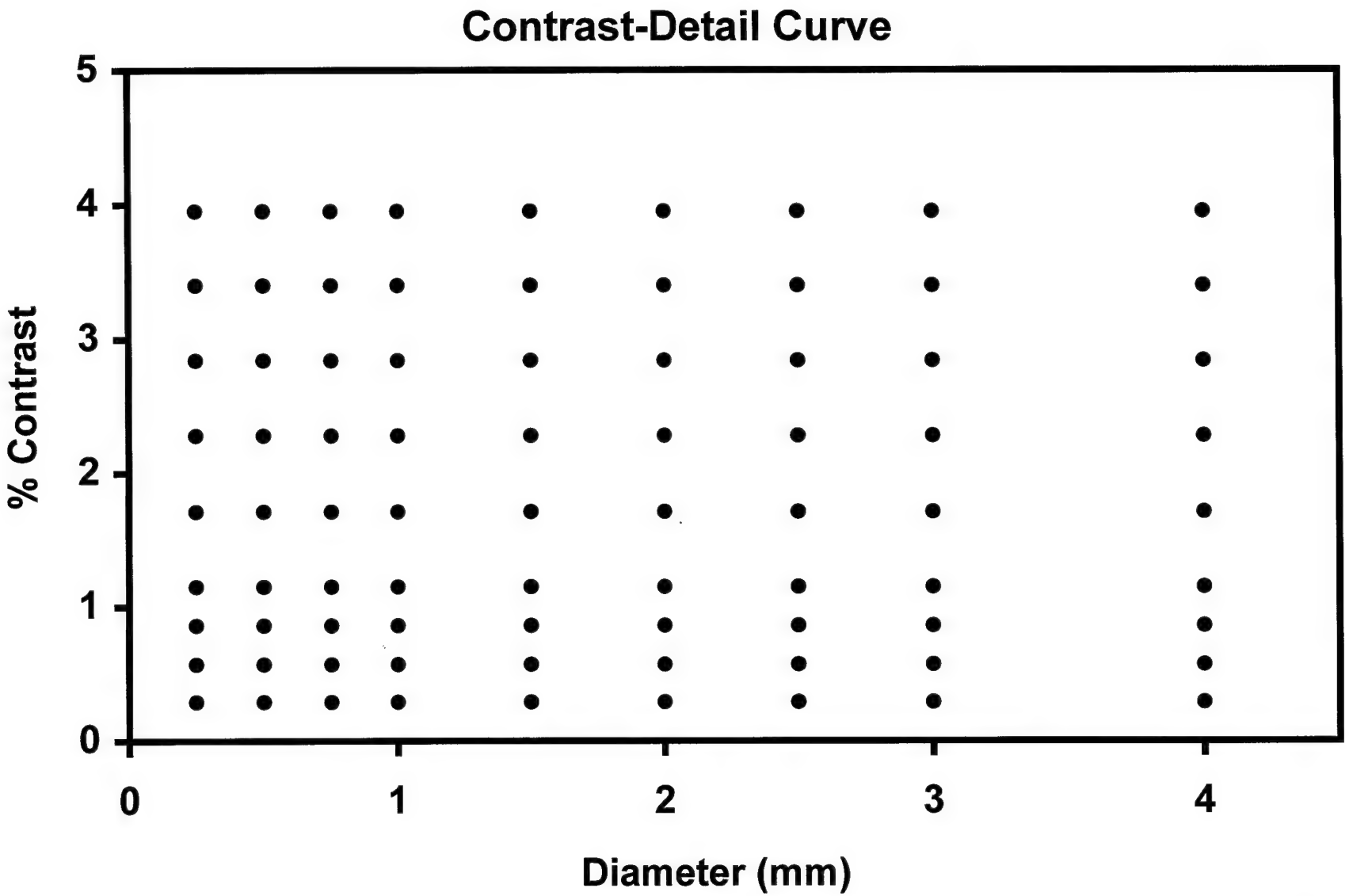


Figure 2: Each point in the grid indicates the % contrast and size of one test object in the contrast-detail CD phantom (81 total objects).

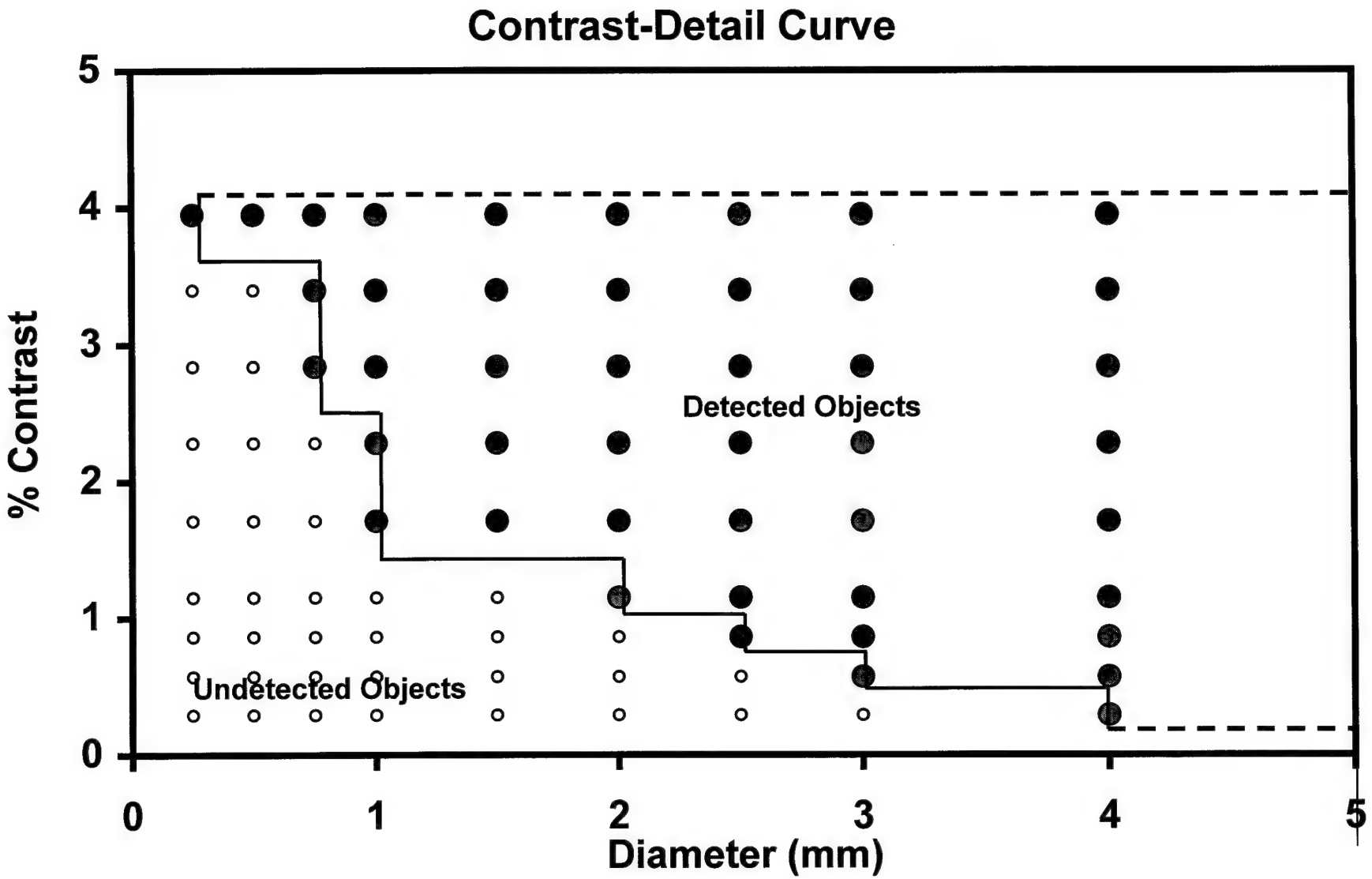


Figure 3: CD phantom scoring by physicist readers determines objects detected (larger points) compared to objects not detected (smaller points). The area of objects detected in size-contrast space (shaded area) is the CD score.

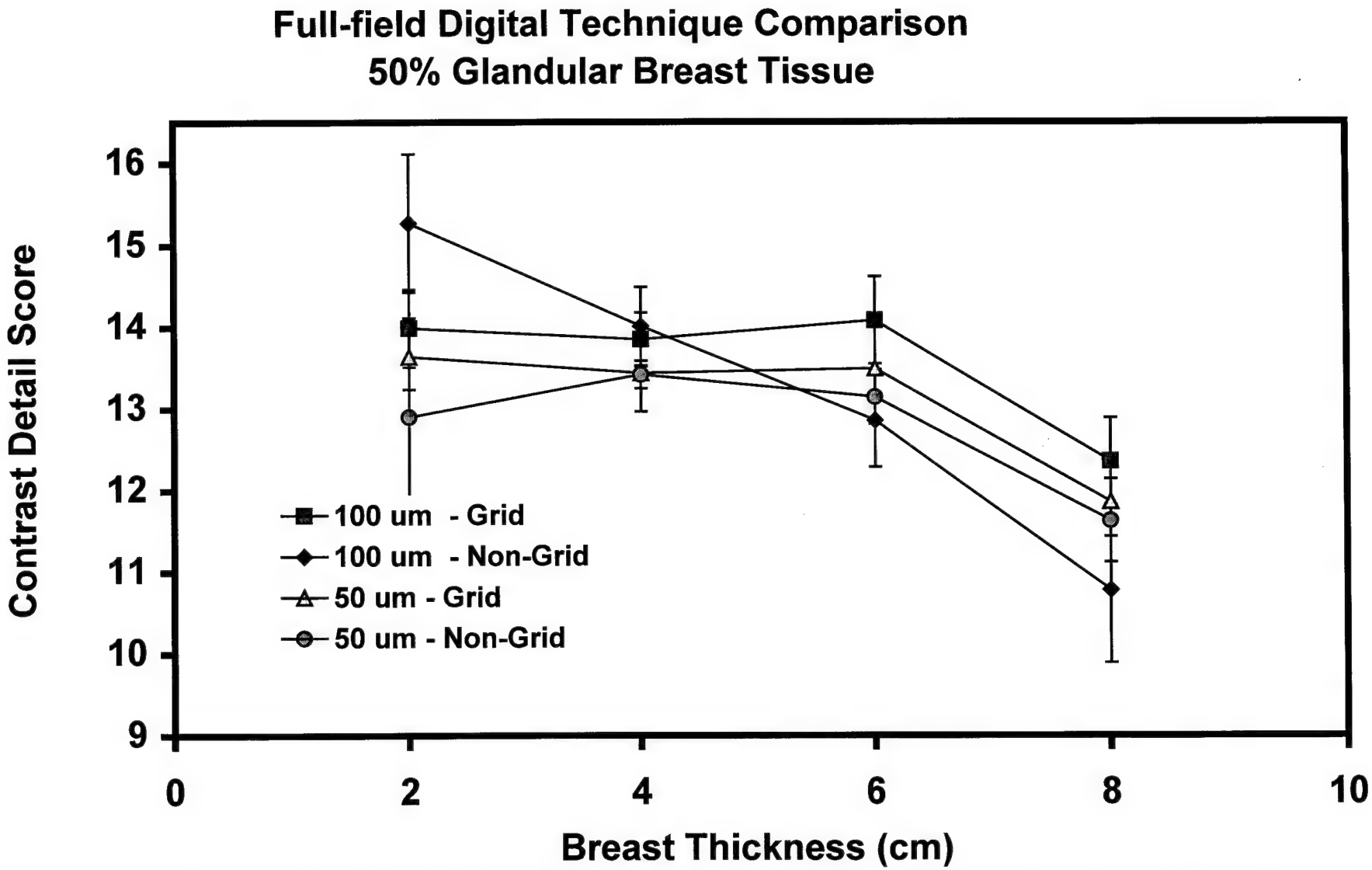


Figure 4: CD scores at simulated breast thicknesses ranging from 2-8 cm for FFDM using different combinations of detector resolution and grid use. Technique factors were identical for the different combinations at each breast thickness.

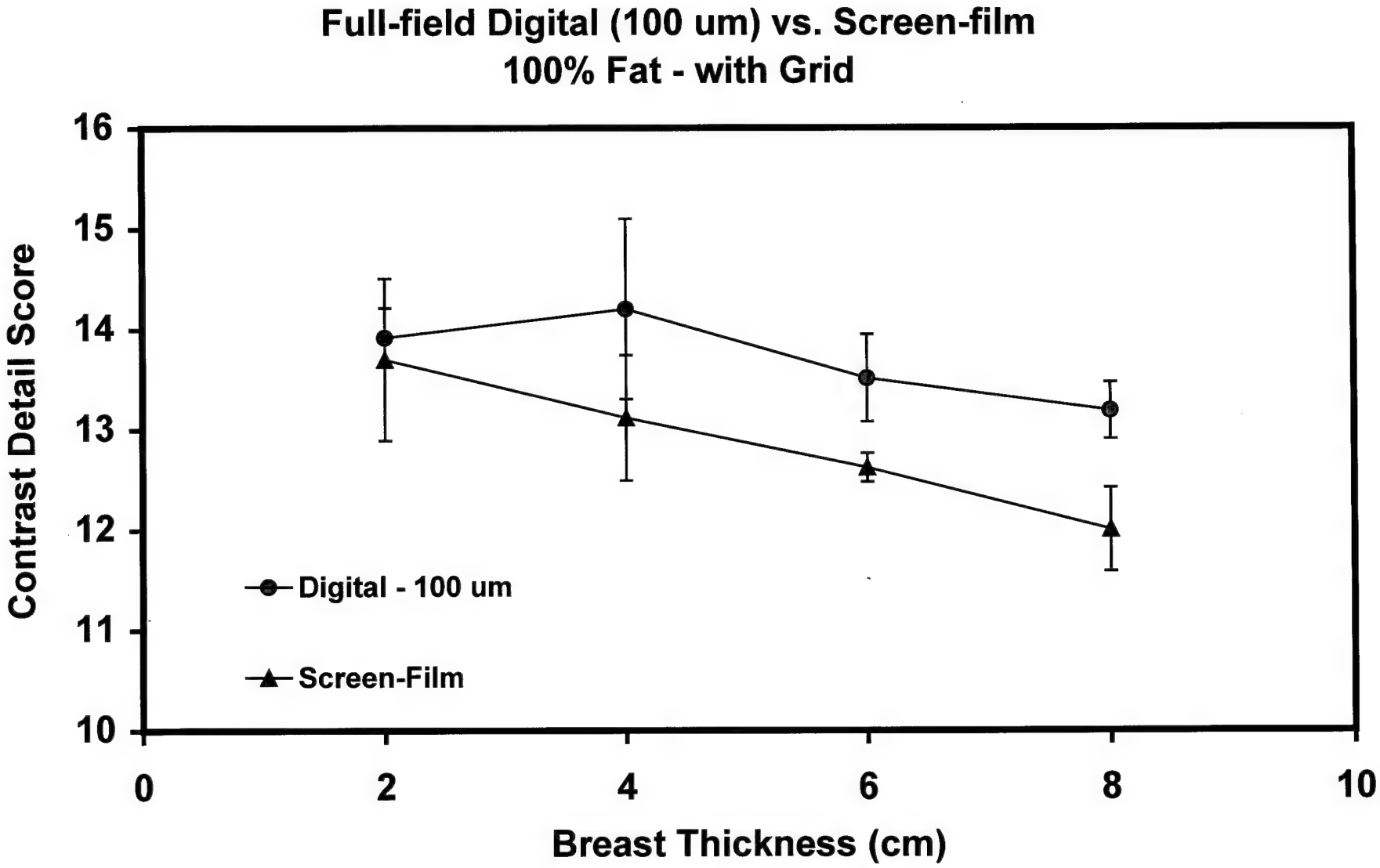


Figure 5: CD scores at simulated breast thicknesses of 100% fatty breasts ranging from 2-8 cm for SFM and FFDM, both using a grid. Technique factors were identical for the different modalities at each breast thickness.

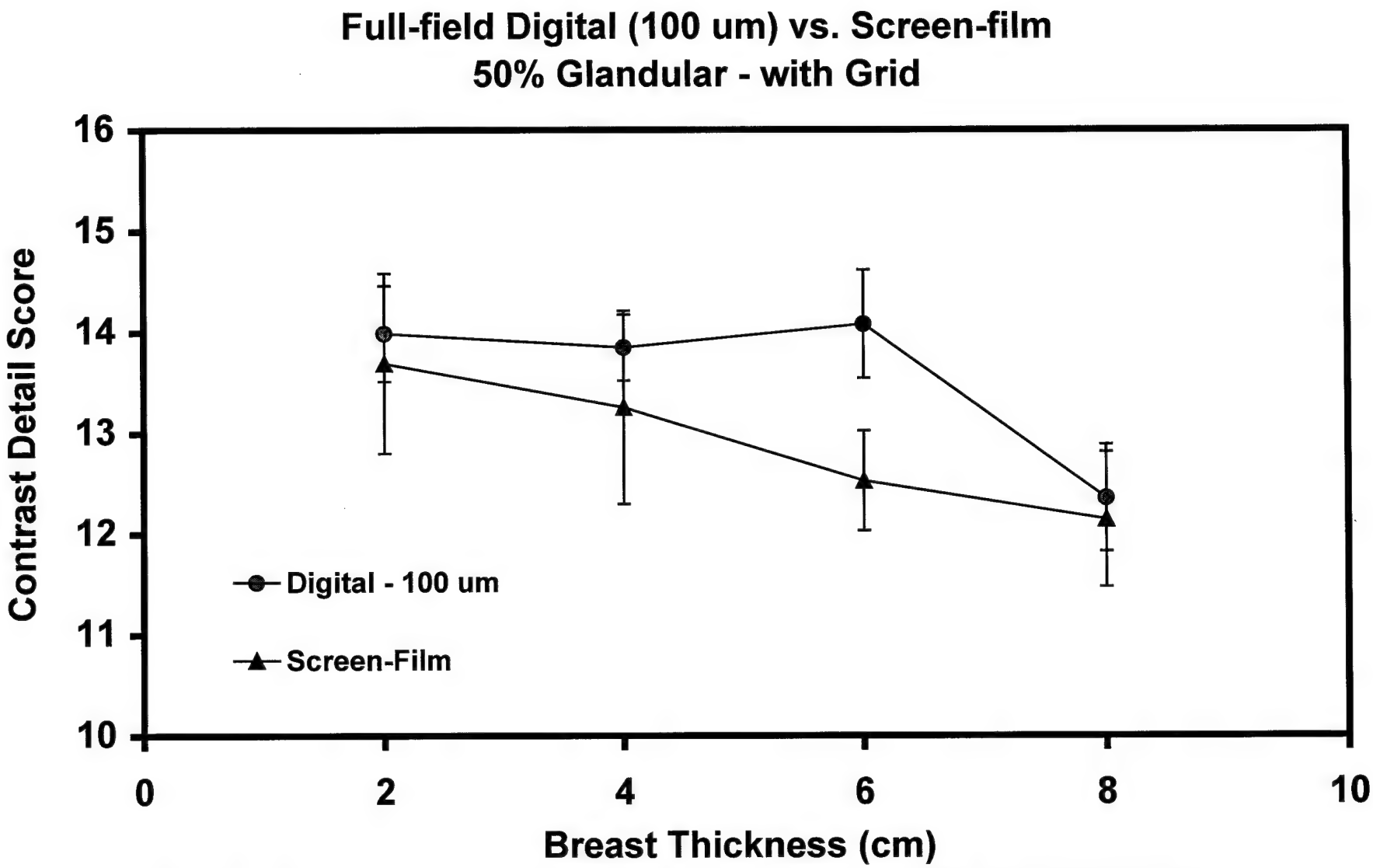


Figure 6: CD scores at simulated breast thicknesses of 50% glandular/50% fatty breasts ranging from 2-8 cm for SFM and FFDM, both using a grid. Technique factors were identical for the different modalities at each breast thickness.

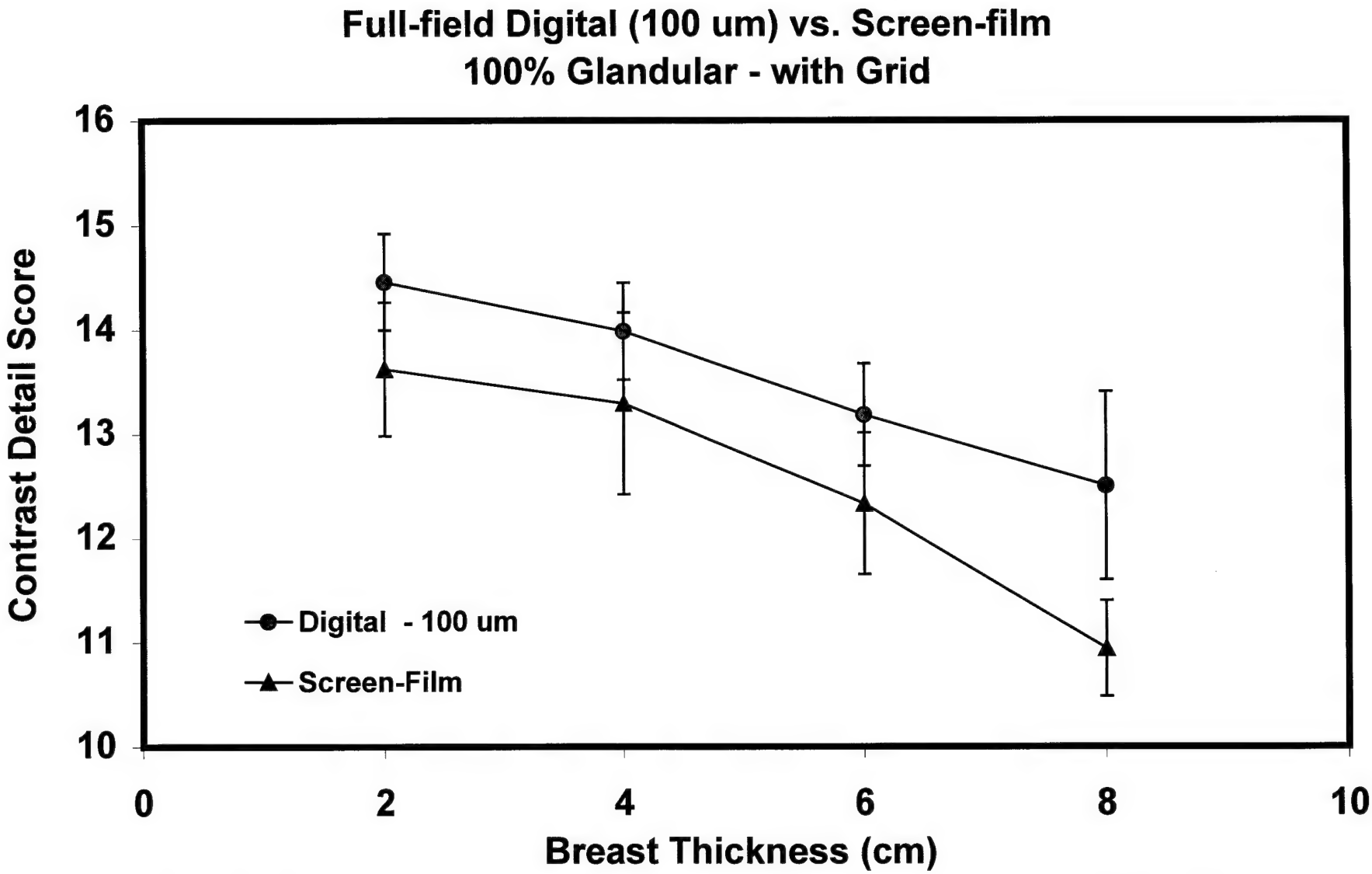


Figure 7: CD scores at simulated breast thicknesses of 100% glandular breasts ranging from 2-8 cm for SFM and FFDM, both using a grid. Technique factors were identical for the different modalities at each breast thickness.

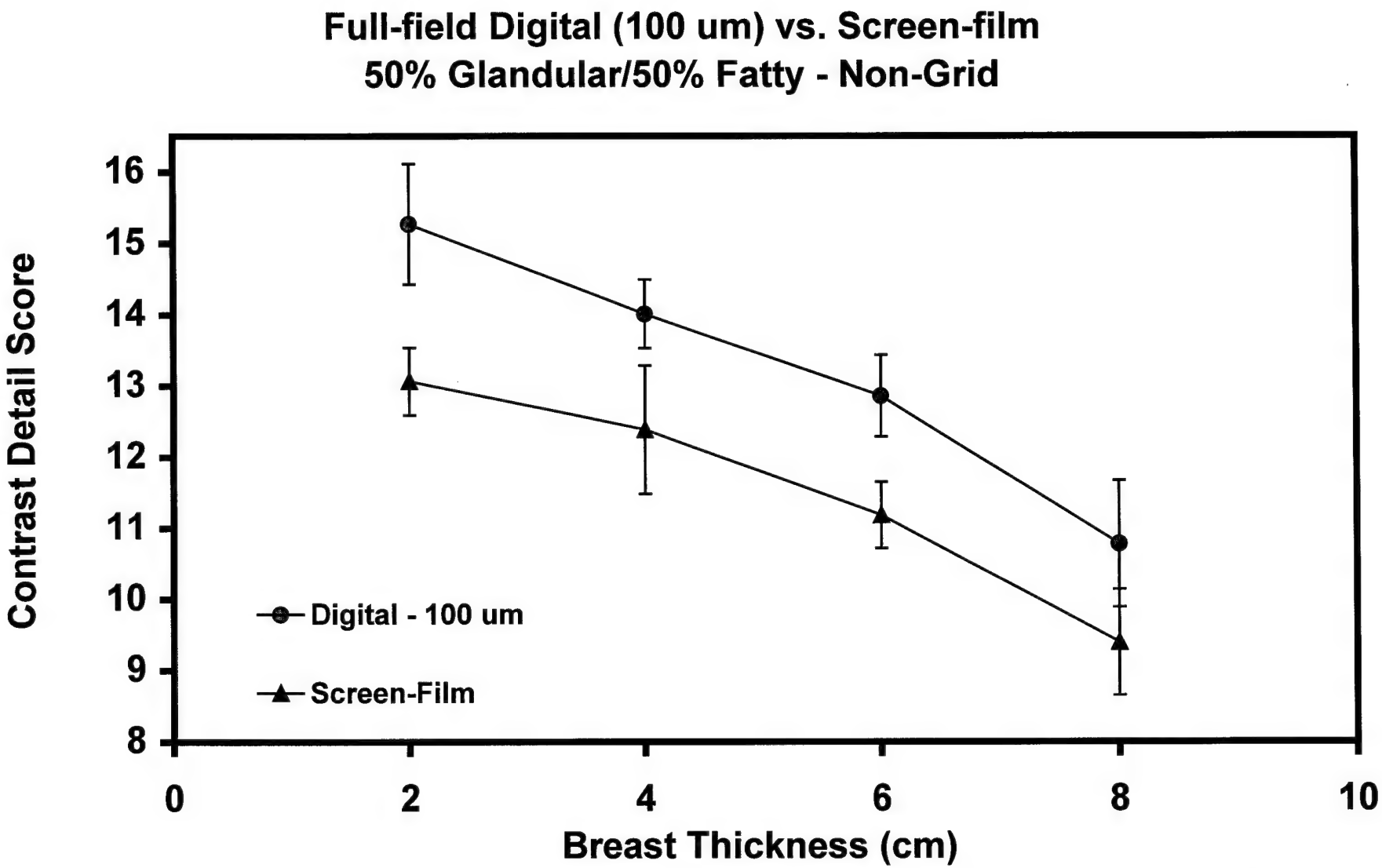


Figure 8: CD scores at simulated breast thicknesses of 50% glandular/50% fatty breasts ranging from 2-8 cm for SFM and FFDM without a grid. Technique factors for FFDM used identical target-filter and kVp, with approximately twice the mAs, as those for SFM for each breast thickness.

MAMMOGRAPHY EQUIPMENT EVALUATION

Site: University Hospitl - East Pavilion
4701 E. 9th Avenue
Denver, CO. 80262

Date: 6/10/97

	Manufacturer	*Model / Type*
X-ray unit:	GE	Full Field Digital - DMR
Processor:	N/A	N/A
Screen:	N/A	N/A
Film:	N/A	N/A

Note: Technique chart was made during inspection of new unit.

Clinical Technque Factors:

Breast Thickness	Exposure Mode	Target / Filter	kVp	mAs	Photo-timed	Grid Use
2 cm	Manual	Mo/Mo	25	50	No	No
4 cm	Manual	Mo/Mo	25	100	No	No
6 cm	Manual	Mo/Rh	27	125	No	No
> 7 cm	Manual	Rh/Rh	28	280	No	No

Mammographic Unit Assembly Evaluation:

- [x] Free-standing dedicated unit is mechanically stable.
- [x] All moving parts move smoothly, without obstructions to motion.
- [x] All locks and detents work properly.
- [x] Image receptor holder assembly is free from vibrations.
- [x] Image receptor held securely by assembly in any orientation.
- [ ] N/A --- Image receptor slides smoothly into holder assembly.
- [x] Compression scale is accurate to +/- 0.5 cm, reprod. to +/- 2mm.
- [x] Patient or operator is not exposed to sharp edges or other hazards.
- [x] Operator technique control charts are posted.
- [x] Operator protected during exposure by adequate radiation shielding.

2. Collimator Assessment

Source to image distance (SID)= 660.00 mm

DEVIATION BETWEEN X-RAY FIELD AND LIGHT FIELD:

COLLIMATOR	18x24 cm
Left Edge Deviation	5.0 mm
Right Edge Deviation	1.0 mm
Sum of Lt & Rt Edge Deviation	6.0 mm
Sum as % of SID	0.9%
ACR Compliance < =2%	**Yes**
Anterior Edge Deviation	1.0 mm
Chest Edge Deviation	2.0 mm
Sum of Ant. & Chest Deviations	3.0 mm
Sum as a % of SID	0.5%
ACR Compliance <= 2%	**Yes**

X-ray Field within Image Receptor Holder Assembly left, right, anterior: **Yes**

DEVIATION BETWEEN X-RAY FIELD & IMAGE RECEPTOR AT CHEST WALL

COLLIMATOR	18x24 cm
Diff of rad. field vs film at chest wall	6.0 mm
% of SID	0.9%
ACR Compliance <=2%	**Yes**

ALIGNMENT OF CHEST WALL EDGES OF COMPRESSION PADDLE & IMAGE RECEPTOR

COLLIMATOR	18x24 cm
Diff of paddle & film at chest wall	4.1 mm
% of SID	0.6%
ACR Compliance <=1%	**Yes**

3. Evaluation of Focal Spot Measurement

Slit Camera Measurement Of Focal Spot Size:

	Mo/Mo	Mo/Mo	Rh/Rh	Rh/Rh
Nominal focal spot size (mm)	0.3	0.1	0.3	0.1
Nominal kVp setting	28	28	28	28
Nominal mA setting	40	75	0	40
mAs	160	160	160	160
Image Size (mm) I	129.1	129.1	125.96	125.96
Object Size (mm) O	45	45	45	45
Enlargement Factor, E=(I/O)-1	1.87	1.87	1.80	1.80
Measured Slit $d_{parallel}$	0.6	0.2	0.5	0.2
Image Widths d_{perp}	0.8	0.35	1	0.4
Slit Width (mm) s	0.00001	0.00001	0.00001	0.00001
Calculated Focal Spot Size (mm)				
f_{perp}	0.287	0.048	0.248	0.050
$f_{parallel}$	0.383	0.084	0.497	0.100
Max Limit Perp	0.450	0.150	0.450	0.150
Max Limit Parallel	0.645	0.150	0.645	0.150
Pass/Fail	Pass	Pass	Pass	Pass

Action Limit: If $f_{parallel}$ exceeds 1.5 x f_{nom} for f_{nom} <0.3mm, or if $f_{parallel}$ exceeds 2.15 x f_{nom} for f_{nom} >/= 0.3mm, or if f_{perp} exceeds 1.5 x f_{nom}, then seek service adjustment or tube relacement.

Note: This DMR is only being used for large spot imaging.

4. kVp Accuracy / Reproducibility

Equipment: Keithley 35050A Dosimetry System

Nominal kVp Setting	22	23	24	25	26	27
Nominal Focal Spot Size	0.3	0.3	0.3	0.3	0.3	0.3
mA / mAs	20	20	20	20	20	20
Exposure time (sec)						
Measured kVp values						
kVp1	22.9	23.9	24.7	25.4	26.2	27.2
kVp2	23.1	23.9	24.8	25.4	26.3	27.1
kVp3	23.0	23.9	24.7	25.4	26.3	27.1
kVp4	23.0	23.8	24.8	25.5	26.2	27.1
kVp5						
kVp6						
kVp7						
kVp8						
kVp9						
kVp10						
Mean kVp	23.0	23.9	24.8	25.4	26.3	27.1
Std Dev.	0.082	0.050	0.058	0.050	0.058	0.050
ACR Test: Accuracy < 5% of Nominal						
Mean - Nominal kVp	1.0	0.9	0.8	0.4	0.3	0.1
5% of Nominal	1.10	1.15	1.20	1.25	1.30	1.35
ACR Compliance	Yes	Yes	Yes	Yes	Yes	Yes
ACR Test: Reproducibility < 2%						
StDev/Mean	0.35%	0.21%	0.23%	0.20%	0.22%	0.18%
ACR Compliance	Yes	Yes	Yes	Yes	Yes	Yes

4. kVp Accuracy / Reproducibility

Equipment: Keithley 35050A Dosimetry System

Nominal kVp Setting	28	29	30	31	32	33
Nominal Focal Spot Size	0.3	0.3	0.3	0.3	0.3	0.3
mA / mAs	20	20	20	20	20	20
Exposure time (sec)						
Measured kVp values						
kVp1	28.0	28.9	29.8	30.7	31.6	32.6
kVp2	28.0	28.7	29.8	30.7	31.6	32.6
kVp3	28.0	28.7	29.8	30.6	31.6	32.5
kVp4	28.1	29.0	29.9	30.8	31.7	32.6
kVp5						
kVp6						
kVp7						
kVp8						
kVp9						
kVp10						
Mean kVp	28.0	28.8	29.8	30.7	31.6	32.6
Std Dev.	0.050	0.150	0.050	0.082	0.050	0.050
ACR Test: Accuracy < 5% of Nominal						
Mean - Nominal kVp	0.0	0.2	0.2	0.3	0.4	0.4
5% of Nominal	1.40	1.45	1.50	1.55	1.60	1.65
ACR Compliance	Yes	Yes	Yes	Yes	Yes	Yes
ACR Test: Reproducibility < 2%						
StDev/Mean	0.18%	0.52%	0.17%	0.27%	0.16%	0.15%
ACR Compliance	Yes	Yes	Yes	Yes	Yes	Yes

4. kVp Accuracy / Reproducibility

Equipment: Keithley 35050A Dosimetry System

Nominal kVp Setting	34	35
Nominal Focal Spot Size	0.3	0.3
mA / mAs	20	20
Exposure time (sec)		
Measured kVp values		
kVp1	33.4	34.4
kVp2	33.4	34.4
kVp3	33.4	34.4
kVp4	33.4	34.4
kVp5		
kVp6		
kVp7		
kVp8		
kVp9		
kVp10		
Mean kVp	33.4	34.4
Std Dev.	0.000	0.000
ACR Test: Accuracy < 5% of Nominal		
Mean - Nominal kVp	0.6	0.6
5% of Nominal	1.70	1.75
ACR Compliance	Yes	Yes
ACR Test: Reproducibility < 2%		
StDev/Mean	0.00%	0.00%
ACR Compliance	Yes	Yes

5. Beam Quality Measurements (HVL)

Equipment: Keithley 35050A Dosimetry System

Nominal kVp	22	23	24	25	26	27
mA setting	100	100	100	100	100	100
Time/mAs setting	63	63	63	63	63	63
Target/Filter	Mo/Mo	Mo/Mo	Mo/Mo	Mo/Mo	Mo/Mo	Mo/Mo
Exposure Measurements (mR)						
0.00 mm Al	314.5	366.0	428.0	491.0	553.0	644.0
0.20 mm Al	199.9	241.1	285.0	330.0	373.0	445.0
0.30 mm Al	163.7	199.2	236.5	277.0	313.0	374.0
0.40 mm Al	135.5	165.8	198.9	235.2	267.3	322.0
Calculations						
HVL (mm Al)	0.32	0.35	0.36	0.37	0.37	0.39
Tar/Filt constant:	0.12	0.12	0.12	0.12	0.12	0.12
Lower Limit	0.25	0.26	0.27	0.28	0.29	0.30
Upper Limit	0.34	0.35	0.36	0.37	0.38	0.39
ACR Compliance	Yes	Yes	Yes	Yes	Yes	Yes

Nominal kVp	28	29	30	31	32	33
mA setting	100	100	100	100	100	100
Time/mAs setting	63	63	63	63	63	32
Target/Filter	Mo/Mo	Mo/Mo	Mo/Mo	Mo/Mo	Mo/Mo	Mo/Mo
Exposure Measurements (mR)						
0.00 mm Al	722.0	804.0	885.0	974.0	1059.0	533.0
0.30 mm Al	422.0	478.0	530.0	587.0	650.0	324.0
0.40 mm Al	361.0	411.0	457.0	509.0	562.0	285.0
0.50 mm Al	316.0	353.0	395.0	441.0	486.0	247.8
Calculations						
HVL (mm Al)	0.40	0.41	0.42	0.43	0.44	0.45
Tar/Filt constant:	0.12	0.12	0.12	0.12	0.12	0.12
Lower Limit	0.31	0.32	0.33	0.34	0.35	0.36
Upper Limit	0.40	0.41	0.42	0.43	0.44	0.45
ACR Compliance	Yes	Yes	Yes	Yes	Yes	Yes

Nominal kVp	34	35
mA setting	100	100
Time/mAs setting	32	32
Target/Filter	Mo/Mo	Mo/Mo
Exposure Measurements (mR)		
0.00 mm Al	627.0	675.0
0.30 mm Al	388.0	419.0
0.40 mm Al	337.0	364.0
0.50 mm Al	297.0	323.0
Calculations		
HVL (mm Al)	0.45	0.46
Tar/Filt constant:	0.12	0.12
Lower Limit	0.37	0.38
Upper Limit	0.46	0.47
ACR Compliance	Yes	Yes

5. Beam Quality Measurements (HVL)

Equipment: Keithley 35050A Dosimetry System

Nominal kVp	27	28	29	30	31	32
mA setting	100	100	100	100	100	100
Time/mAs setting	40	40	40	40	40	40
Target/Filter	Mo/Rh	Mo/Rh	Mo/Rh	Mo/Rh	Mo/Rh	Mo/Rh
Exposure Measurements (mR)						
0.00 mm Al	330.0	373.0	415.0	460.0	507.0	554.0
0.30 mm Al	208.1	236.5	265.0	298.0	325.0	356.0
0.40 mm Al	180.3	205.4	230.8	259.8	288.0	316.0
0.50 mm Al	156.9	179.4	203.0	227.2	253.0	278.9
Calculations						
HVL (mm Al)	0.46	0.47	0.48	0.49	0.50	0.51
Tar/Filt constant:	0.19	0.19	0.19	0.19	0.19	0.19
Lower Limit	0.30	0.31	0.32	0.33	0.34	0.35
Upper Limit	0.46	0.47	0.48	0.49	0.50	0.51
ACR Compliance	Yes	Yes	Yes	Yes	Yes	Yes

Nominal kVp	33	34	35
mA setting	100	100	100
Time/mAs setting	40	40	40
Target/Filter	Mo/Rh	Mo/Rh	Mo/Rh
Exposure Measurements (mR)			
0.00 mm Al	605.0	653.0	705.0
0.30 mm Al	393.0	427.0	461.0
0.40 mm Al	344.0	374.0	405.0
0.50 mm Al	306.0	330.0	358.0
Calculations			
HVL (mm Al)	0.50	0.51	0.51
Tar/Filt constant:	0.19	0.19	0.19
Lower Limit	0.36	0.37	0.38
Upper Limit	0.52	0.53	0.54
ACR Compliance	Yes	Yes	Yes

5. Beam Quality Measurements (HVL)

Equipment: Keithley 35050A Dosimetry System

Nominal kVp	27	28	29	30	31	32
mA setting	100	100	100	100	100	100
Time/mAs setting	40	40	40	40	40	40
Target/Filter	Rh/Rh	Rh/Rh	Rh/Rh	Rh/Rh	Rh/Rh	Rh/Rh
Exposure Measurements (mR)						
0.00 mm Al	334.0	375.0	416.0	459.0	505.0	550.0
0.40 mm Al	180.0	206.1	230.7	257.8	291.0	319.0
0.50 mm Al	156.9	179.0	202.9	227.7	257.2	284.0
0.60 mm Al		157.7	179.9	203.0	227.4	253.0
Calculations						
HVL (mm Al)	0.45	0.47	0.48	0.49	0.51	0.53
Tar/Filt constant:	0.22	0.22	0.22	0.22	0.22	0.22
Lower Limit	0.30	0.31	0.32	0.33	0.34	0.35
Upper Limit	0.49	0.50	0.51	0.52	0.53	0.54
ACR Compliance	Yes	Yes	Yes	Yes	Yes	Yes

Nominal kVp	33	34	35	36
mA setting	100	100	100	100
Time/mAs setting	40	40	40	40
Target/Filter	Rh/Rh	Rh/Rh	Rh/Rh	Rh/Rh
Exposure Measurements (mR)				
0.00 mm Al	598.0	647.0	701.0	751.0
0.40 mm Al	345.0	384.0	414.0	446.0
0.50 mm Al	312.0	339.0	370.0	400.0
0.60 mm Al	280.0	307.0	332.0	361.0
Calculations				
HVL (mm Al)	0.54	0.54	0.55	0.56
Tar/Filt constant:	0.22	0.22	0.22	0.22
Lower Limit	0.36	0.37	0.38	0.39
Upper Limit	0.55	0.56	0.57	0.58
ACR Compliance	Yes	Yes	Yes	Yes

6. Automatic Exposure Control (AEC) System Performance

Not Applicable

7. Uniformity of Screen Speed

Not Applicable

8. Breast Entrance Exposure and Average Glandular Dose.

Dosimetry system: Keithley 35050A Dosimetry System
Imaging mode: AEC
Imaging Receptor: 18x 24 cm
SID: 660.00
ACR Phantom: RMI 156-7061

	Clinical ACR	
THK (acr =4.2) cm	4.2	cm
Nominal kVp	25	kVp
Target/Filter	Mo/Mo	
Density control	0	
mA setting	100	mA
Meas. HVL	0.37	mmAl
Entrance expos.	mR	mAs
Expos #1	816	100
Expos #2	816	100
Expos #3	816	100
Expos #4	816	100
Mean	816	100
Std Dev	0.00	0.00
CV	0.00	0.00
ACR Compliance: CV <0.05	Yes	Yes
Dose conversion factor:	183	mrad / R
Average Glandular Dose	149	mrad
ACR Compliance: Dose < 300 mrad	Yes	

Analytical Dose Calculation	154	mrad

valid for Mo/Mo only

AVERAGE GLANDULAR DOSE CALCS

Dose with BR-12 50/50, Mo/Mo target-filter combination.

Breast Doseimetry in Screen Film Mammography

Data from Barnes & Wu valid for Mo/Mo only!!!!

Thickness	2 cm		6 cm	
Meas. HVL	0.37		0.39	
kVp	25		26	
mAs	50		250	
Target/Filter	Mo/Mo		Mo/Mo	
Focal Spot	0.3		0.3	
Entrance expos mR	380		2500	
A calc	0.054789		-0.00455	
B calc	0.777684		0.369114	
Dose conversion factor:	0.343	mrad / R	0.139	mrad / R
Average Glandular Dose	**130**	mrad	**349**	mrad

A==K1+K2*EXP(-THK/K3)

B==K4+K5*EXP(-THK/K6)

C==A+B*HVL

DOSE = C * ESE

K1:	-0.007	K4:	0.1563
K2:	0.3406	K5:	1.0618
K3:	1.1666	K6:	3.7326

curve fit parameters

9. Image Quality Evaluation:

Phantom: CR - RMI 156-7061

Mode: Manual

Detector: N/A

	Previous	Current	ACR Limit
kVp		25	
Phototimed mAs		100	
Background OD		N/A	
OD inside disc		N/A	
OD difference		N/A	
Number of fibers		5.0	Pass
Number of speck groups		4.0	Pass
Number of masses		4.0	Pass

10. Artifact Evaluation

Attenuator: Acrylic

Thk: 1 inch

kVp: 25

Density Ctrl: N/A

Focal Spot: 0.3 mm

	Mo/Mo	Mo/Rh	Rh/Rh
Image Receptor	18 x 24 cm	18 x 24 cm	18 x 24 cm
Resultant OD	N/A	N/A	N/A
Artifacts visible?	No	No	No
Processor			
Equipment artifact			
Other artifact			

Explaination of artifacts:

NONE

Medical Physicist's Mammography QC Test Summary

Site: University Hospitl - East Pavilion
4701 E. 9th Avenue
Denver, CO. 80262

Report Date: 7/28/97
Survey Date: 6/10/97
X-ray Unit manuf: GE
Model: Full Field Digital - DMR
Film Processor: N/A
Model: N/A

Medical Physicist: _____
Eric Berns, MS

Medical Physicist: _____
R. Edward Hendrick, PhD, QI #023

1. Mammographic Unit Assembly Evaluation	PASS
Compression scale NOT accurate to +/- 0.5 cm	
2. Collimator Assessment	
Deviation between x-ray field and light field is less than 2% of SID	PASS
X-ray field is within image receptor at left, right and anterior edges	PASS
X-ray field does not extend beyond chest wall edge of image receptor by more than 2% of SID	PASS
Chest wall edge of compression paddle does not extend beyond image receptor by more than 1% of SID	PASS
3. Focal Spot Size Measurement	
Measured focal spot is within acceptable limits for large focal spot	PASS
Measured focal spot is within acceptable limits for small focal spot	N/A
4. kVp Accuracy and Reproducibility	
Measured average kVp within +/-5% of nominal kVp	PASS
kVp coefficient of variation <= 0.02	PASS
5. Beam Quality (Half-Value Layer [HVL]) Assessment	
HVL is within acceptable lower and upper limits at all techniques tested	PASS
6. Automatic Exposure Control (AEC) System Performance	
Phototimer compensation for kVp and breast thickness is adequate	N/A
Density control function is adequate	N/A
7. Uniformity of Screen Speed	
Optical density range of all cassettes is within 0.3	N/A

Medical Physicist's Mammography QC Test Summary con't

8. Breast Entrance Exposure and Averge Glandular Dose		
Exposure reproducibility is within acceptable limits		PASS
Average glandular dose for average breast is below 3mGy		PASS
Average glandular dose to a 4.2 cm breast is	149 mrad	
9. Image Quality Evaluation		
Phantom image quality is acceptable		PASS
Phantom Image Quality scores:		
Fibers= 5 Specks= 4 Masses= 4		
10. Artifact evaluation:		
Artifacts were not apparent or not significant:		PASS
Artifacts Identified:		
Evaluation of Site's Technologist QC Program		
1. Darkroom cleaniness		PASS
2. Processsor QC		PASS
3. Screen Cleaning		PASS
4. Mammographic phantom imaging		PASS
5. Darkroom Fog		PASS
6. Film-screen contact test		PASS
7. Compression pressure monitored		PASS
8. Repeat analysis		PASS
9. Viewboxes and viewing conditions		PASS
10. Analysis of fixer retention		PASS
11. Visual checklist		PASS

Medical Physicist's Recommendations for Quality Improvement:

None.

Medical Physicist's Mammography QC Test Summary

Site: **UNIVERSITY OF MASSACHUSETTS MEDICAL CENTER**

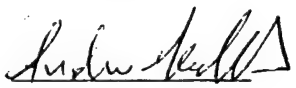
Report Date: July 10, 1997

Survey Date: July 9, 1997

X-Ray Unit Manufacturer: GE

Model: DMR-Full Field Digital Investigational Device

Medical Physicist: Andrew Karellas, Ph.D.

Signature 

Medical Physicist's QC Tests

		Pass/Fail
1.	Mammographic Unit Assembly Evaluation	P
2.	Collimator Assessment	
	Deviation between x-ray field and light field is less than 2% of SID	P
	X-ray field is within image receptor at left, right, and anterior edges	P
	X-ray field does not extend beyond chest wall edge of image receptor by more than 1% of SID	P *
	Chest wall edge of compression paddle does not extend beyond image receptor by more than 1% of SID	P
3.	Focal Spot Size Measurement /Line pair resolution	
	Line pair resolution is within acceptable limits for large focal spots	P
4.	kVp Accuracy and Reproducibility	
	Measured average kVp within ± 5% of nominal kVp	P * *
	kVp coefficient of variation ≤ 0.02	P
5.	Beam Quality (Half-Value Layer [HVL]) Assessment	P
	HVL is within acceptable lower and upper limits at all kVp values tested	P
6.	Automatic Exposure Control (AEC) System Performance	
	Exposure reproducibility is within acceptable limits	NA
	Phototimer compensation for kVp and breast thickness is adequate	NA
	Density control function is adequate	NA
7.	Uniformity of Screen Speed	
	Optical density range of all cassettes is within 0.3	NA
8.	Breast Entrance Exposure and Average Glandular Dose	
	Average glandular dose for average breast is below 3 mGy (300 mrad)	P
	Please see detailed dosimetry in the report	

		Pass/Fail
9.	Image Quality Evaluation Phantom image quality is acceptable Please see enclosed results	P
10.	Artifact Evaluation Artifacts were deemed acceptable for the clinical trial	P

Medical Physicist's Comments and Recommendations

* The digital detector starts at 4.0 mm from the chest wall for all collimation selections. This is about 2 mm more than encountered with film-screen cassettes. Therefore, 2 mm of breast tissue near the chest wall will not be imaged with the digital detector. This was discussed with GE engineers (Cynthia Landberg) and they are well aware of this limitation.

** The kVp was off by about 1 Kv. The unit was recalibrated on July 9, 1997 by GE service. All HVL and mean glandular dose were calculated after the kVp recalibration.

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Mammography Equipment Evaluation

Site: UNIVERSITY OF MASSACHUSETTS MEDICAL CENTER Date: 7.9.97

* FULL FIELD DIGITAL MAMMOGRAPHY INVESTIGATIONAL DEVICE

Equipment

X-ray unit manufacturer GENERAL ELECTRIC Model DMR/Digital

Processor manufacturer _____ Model _____

Screen manufacturer _____ Type _____

Film manufacturer _____ Type _____

Clinical Technique Factors

Breast Thickness	Exposure Mode	kVp Setting	Density Control Setting	Phototimed		Grid Used	
				Y	N	Y	N
				Y	N	Y	N
				Y	N	Y	N
				Y	N	Y	N
				Y	N	Y	N

1. Mammographic Unit Assembly Evaluation (Y = yes, N = no; N/A = not applicable)

Free-standing dedicated unit is mechanically stable.	(Y)	N	N/A
All moving parts move smoothly, without obstructions to motion.	(Y)	N	
All locks and detents work properly.	(Y)	N	
Image receptor holder assembly is free from vibrations.	(Y)	N	
Image receptor is held securely by assembly in any orientation.	(Y)	N	
Image receptor slides smoothly into holder assembly.	(Y)	N	
Compressed breast thickness scale is accurate to ±0.5 cm, reproducible to ±2 mm.	(Y)	N	
Patient or operator is not exposed to sharp or rough edges or other hazards.	(Y)	N	
Operator technique control charts are posted.	Y	N	
Operator protected during exposure by adequate radiation shielding.	(Y)	N	

Duplicate these forms so they will be available for repeated use.

Appendix 3: Data Recording and Analysis Forms ([redacted])

DATE: 7.3.97

Digital DMR
UMMC

3. Evaluation of Focal Spot Measurement

B. High-contrast resolution pattern measurement of limiting resolution

Nominal focal spot size, f_{nom}		0.3mm				
Nominal kVp setting		30				
Nominal mA setting		100				
mAs		50.0				
Magnification factor		~~CONTACT~~ (4.5cm) Above film.				
Limiting resolution	bars parallel to A–C axis	20 lp/mm				
	bars perpendicular to A–C axis	20 lp/mm				

* Direct exposure film used.

Action Limit: If the limiting resolution is <13 line-pairs per mm with the bars parallel to the anode-cathode axis or is <11 line-pairs per mm with the bars perpendicular to the anode-cathode axis, then a more detailed investigation of the reason shound be made using a slit camera.

After calibration 7.9.97

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Mo|Mo

Digital DMR
meter setting (CP)

4. kVp Accuracy/Reproducibility

kVp meter used: RMI MAMMOGRAPHIC kVp meter MODEL 232

Nominal kVp setting	25	26	27	28	29	30	31	32	33	34	35
Nominal focal spot size (mm)	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3
Exposure time											
mA (or (mAs) setting	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
Measured kVp values											
kVp_1	24.9	25.8	26.8	27.9	28.9	30.0	31.1	32.1	33.1	34.1	35.2
kVp_2	24.9	25.8	26.8	27.9	28.9	30.0	31.1	32.1	33.1	34.1	35.2
kVp_3	24.9	25.8	26.8	27.9	28.9	30.0	31.1	32.1	33.1	34.1	35.2
kVp_4	24.9	25.8	26.8	27.9	28.9	30.0	31.1	32.1	33.1	34.1	35.2
Mean kVp <kVp>	24.9	25.8	26.8	27.9	28.9	30.0	31.1	32.1	33.1	34.1	35.2
Standard dev. σ_{kVp}	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Additional kVp measurements (if needed)											
kVp_5											
kVp_6											
kVp_7											
kVp_8											
kVp_9											
kVp_{10}											
Recalculated:											
Mean kVp <kVp>	-										
Standard dev. σ_{kVp} (using 10 readings)											
<kVp> – Nominal kVp	-0.1	-0.2	-0.2	-0.1	-0.1	0.0	+0.1	+0.1	+0.1	+0.1	+0.2
0.05 x Nominal kVp	1.25	1.3	1.35	1.4	1.45	1.5	1.55	1.6	1.65	1.7	1.75
kVp coefficient of variation $\frac{\sigma_{kVp}}{<kVp>}$	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

Action Limit: If <kVp> differs from the nominal kVp by more than ±5% of the nominal kVp, or if the kVp coefficient of variation exceeds 0.02, then seek service correction.

*After calibration 7.9.97

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Digital DMK

Rh | Rh

4. kVp Accuracy/Reproducibility

kVp meter used: Tektronix digital storage oscilliscope
GE service. 2232 (G. Keister : service person)

Nominal kVp setting	25	26	27	28	29	30	31	32	33	34	35
Nominal focal spot size (mm)	0.3	→									
Exposure time											
mA (or mAs) setting	20.0	20.0	→								
Measured kVp values											
kVp_1	24.9	25.8	26.8	27.9	28.9	30.0	31.1	32.1	33.1	34.1	35.1
kVp_2	24.9	25.8	26.8	27.9	28.9	30.0	31.1	32.1	33.1	34.1	35.1
kVp_3	24.9	25.8	26.8	27.9	28.9	30.0	31.1	32.1	33.1	34.1	35.1
kVp_4	24.9	25.8	26.8	27.9	28.9	30.0	31.1	32.1	33.1	34.1	35.1
Mean kVp <kVp>	24.9	25.8	26.8	27.9	28.9	30.0	31.1	32.1	33.1	34.1	35.1
Standard dev. σ_{kVp}	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Additional kVp measurements (if needed)											
kVp_5											
kVp_6											
kVp_7											
kVp_8											
kVp_9											
kVp_{10}											
Recalculated: Mean kVp <kVp>											
Standard dev. σ_{kVp} (using 10 readings)											
<kVp> – Nominal kVp	-0.1	-0.2	-0.2	-0.1	-0.1	0.0	±0.1	+0.1	+0.1	+0.1	+0.2
0.05 x Nominal kVp	1.25	1.3	1.35	1.4	1.45	1.5	1.55	1.6	1.65	1.7	1.75
kVp coefficient of variation $\frac{\sigma_{kVp}}{<kVp>}$	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

Action Limit: If <kVp> differs from the nominal kVp by more than ±5% of the nominal kVp, or if the kVp coefficient of variation exceeds 0.02, then seek service correction.

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Mo/Mo Digital

5. Beam Quality (HVL) Measurement

Dosimetry system used: MDH ELECTROMETER MODEL 1515 with MAMMO PROBE

Nominal kVp setting		25	26	27	28	29	30	31	32
mA setting		100	100	100	100	100	100	100	100
Time or (mAs) setting		90.0	80.0	71.8	63.0	56.0	50.0	40.0	32.0
Exposure measurements:									
No aluminum filtration, E_0		598	608	612	608	604	595	523	516
0.2 mm of added aluminum, E_2		390	402	408	411	411	409	362	359
0.3 mm of added aluminum, E_3		322	333	340	345	346	344	306	304
0.4 mm of added aluminum, E_4		269	279	287	291	294	294	261	260
~~0.5~~ mm of added aluminum, E_5									
Repeat E_0 measurement, $E_{0'}$		598	608	612	608	604	595	523	516
Record thicknesses and exposures that bracket $E_0/2$:	t_a								
	t_b								
	E_a								
	E_b								
Calculated HVL:		0.35	0.35	0.36	0.38	0.38	0.39	0.40	0.40

($t_a < t_b$) ($E_a > E_b$)

* HVLs WERE CALCULATED BY AN EXPONENTIAL CURVE FIT.

$$\text{Calculated HVL} = \frac{t_b \ln[2E_a/E_0] - t_a \ln[2E_b/E_0]}{\ln[E_a/E_b]}$$

Action Limit: If measured HVL $< \frac{\text{kVp}}{100} + 0.03$ (in mm Al)

or

if measured HVL $> \frac{\text{kVp}}{100} + C$ (in mm Al),

where C = 0.12 for Mo/Mo, C = 0.19 for Mo/Rh, and C = 0.22 for Rh/Rh,

then seek service correction.

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*7.9.97

Mo/Rh

Digital

5. Beam Quality (HVL) Measurement

Dosimetry system used: MDH ELECTROMETER MODEL 1515 with mammo chamber

Nominal kVp setting	27	28	29	30	31	32
mA setting	100	100	100	100	100	100
Time or mAs setting	90.0	71.0	63.0	56.0	50.0	45.0
Exposure measurements:						
No aluminum filtration, E_0	621	554	550	543	534	527
0.2 mm of added aluminum, E_2	437	394	393	390	385	382
0.3 mm of added aluminum, E_3	373	337	337	334	331	330
0.4 mm of added aluminum, E_4	319	290	290	289	287	286
~~0.5~~ mm of added aluminum, E_5						
Repeat E_0 measurement, $E_{0'}$	621	554	550	543	535	528
Record thicknesses ($t_a < t_b$) t_a						
and exposures t_b						
that bracket $E_0/2$: ($E_a > E_b$) E_a						
E_b						
Calculated HVL:	0.42	0.43	0.43	0.44	0.44	0.45

* HVLs were calculated by an exponential curve fit.

$$\text{Calculated HVL} = \frac{t_b \ln[2E_a/E_0] - t_a \ln[2E_b/E_0]}{\ln[E_a/E_b]}$$

Action Limit: If measured HVL $< \frac{\text{kVp}}{100} + 0.03$ (in mm Al)

or

if measured HVL $> \frac{\text{kVp}}{100} + C$ (in mm Al),

where C = 0.12 for Mo/Mo, C = 0.19 for Mo/Rh, and C = 0.22 for Rh/Rh,

then seek service correction.

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 * 7.9.97

Rh|Rh Digital

5. Beam Quality (HVL) Measurement

Dosimetry system used: mDH ELECTROMETER MODEL 1515 with mammo chamber

Nominal kVp setting	28	29	30	31	32
mA setting	75	75	75	75	75
Time or (mAs) setting	71.0	63.0	56.0	50.0	40.0
Exposure measurements:					
No aluminum filtration, E_0	598	593	583	573	502
0.2 mm of added aluminum, E_2	421	422	418	416	367
0.3 mm of added aluminum, E_3	361	362	360	359	319
0.4 mm of added aluminum, E_4	311	314	314	313	279
~~0.5~~ mm of added aluminum, E_5					
Repeat E_0 measurement, $E_{0'}$	597	593	582	572	502
Record thicknesses ($t_a < t_b$) t_a					
and exposures t_b					
that bracket $E_0/2$: ($E_a > E_b$) E_a					
E_b					
Calculated HVL:	0.42	0.43	0.45	0.46	0.47

* HVLs were calculated by an exponential curve fit.

$$\text{Calculated HVL} = \frac{t_b \ln[2E_a/E_o] - t_a \ln[2E_b/E_o]}{\ln[E_a/E_b]}$$

Action Limit: If measured HVL $< \frac{\text{kVp}}{100} + 0.03$ (in mm Al)

or

if measured HVL $> \frac{\text{kVp}}{100} + C$ (in mm Al),

where C = 0.12 for Mo/Mo, C = 0.19 for Mo/Rh, and C = 0.22 for Rh/Rh,

then seek service correction.

Appendix 3: Data Recording and Analysis Forms ([redacted]) 7.9.97

8. Breast Entrance Exposure, Average Glandular Dose, and AEC Reproducibility Mo/Mo

Digital DMR

Dosimetry system used: MDH ELECTROMETER Energy correction factor: 0.99
Imaging mode: MODEL 1515 with MAMMO CHAMBER MANUAL
Image receptor: DIGITAL Size (cm): 18 by 23
Field restriction: 18X23
SID (cm): 66.0 CM
Phantom: GAMMEX RMI MAMMOGRAPHIC PHANTON SERIAL #156-15217

Nominal kVp setting:	25		26		27	
Target/Filtration:	Mo/Mo		Mo/Mo		Mo/Mo	
~~AEC~~ density control setting:	manual		manual		manual	
mA setting:	100		100		100	
Measured HVL (mm Al):	0.35		0.35		0.36	
(SECONDS) →	(2.05)		(1.56)		(1.19)	
Measured entrance exposure:	R	mAs	R	mAs	R	mAs
Exposure #1	1.26	180.0	1.13	140.0	1.00	110.0
Exposure #2	1.26	180.0	1.13	140.0	1.00	110.0
Exposure #3	1.26	180.0	1.13	140.0	1.00	110.0
Exposure #4	1.26	180.0	1.13	140.0	1.00	110.0
(mR/mAs) →	(7.0)		(8.07)		(9.10)	
Mean values	1.26	180.0	1.13	140.0	1.00	110.0
Standard deviations (SD)	0.0	0.0	0.0	0.0	0.0	0.0
Coefficients of variation (CV)	0.0	0.0	0.0	0.0	0.0	0.0

Energy-corrected exposure:	1.25	1.12	0.99
Dose conversion factor from Table 1-3 (mrad/R):	175	176	182
Computed average glandular dose (mrad):	219.0	197.0	180.0

Action Limit: If coefficient of variation for either R or mAs exceeds 0.05, seek service. If average glandular dose exceeds 300 mrads (3 mGy) for 4.2-cm effective breast thickness, seek service or technique adjustment.

Appendix 3: Data Recording and Analysis Forms ([redacted]) 7.9.97

8. Breast Entrance Exposure, Average Glandular Dose, and AEC Reproducibility — Digital DMR

Mo/Mo

Dosimetry system used: MDH ELECTROMETER Energy correction factor: 0.99
Imaging mode: MODEL 1515 with mammo chamber manual
Image receptor: DIGITAL Size (cm): 18 by 23
Field restriction: 18 x 23
SID (cm): 66.0 CM
Phantom: GAMMEX RMI MAMMOGRAPHIC phantom ser. # 156-15217

Nominal kVp setting:	28	29	30
Target/Filtration:	Mo/Mo	Mo/Mo	Mo/Mo
AEC density control setting:	MANUAL	MANUAL	MANUAL
mA setting:	100	100	100
Measured HVL (mm Al):	0.38	0.38	0.39
(SECONDS) →	(0.946)	(0.728)	(0.628)

Measured entrance exposure:	R	mAs	R	mAs	R	mAs
Exposure #1	0.923	90.0	0.810	71.0	0.793	63.0
Exposure #2	0.923	90.0	0.810	71.0	0.793	63.0
Exposure #3	0.923	90.0	0.810	71.0	0.793	63.0
Exposure #4	0.923	90.0	0.810	71.0	0.793	63.0
(mR/mAs) →	(10.3)		(11.4)		(12.6)	
Mean values	0.923	90.0	0.810	71.0	0.793	63.0
Standard deviations (SD)	0.0	0.0	0.0	0.0	0.0	0.0
Coefficients of variation (CV)	0.0	0.0	0.0	0.0	0.0	0.0

Energy-corrected exposure:	0.914	0.802	0.785
Dose conversion factor from Table 1-3 (mrad/R):	191	192	198
Computed average glandular dose (mrad):	175.0	154.0	155.0

Action Limit: If coefficient of variation for either R or mAs exceeds 0.05, seek service. If average glandular dose exceeds 300 mrads (3 mGy) for 4.2-cm effective breast thickness, seek service or technique adjustment.

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 [redacted] 7.9.97

8. Breast Entrance Exposure, Average Glandular Dose, and AEC Reproducibility

DIGITAL DMR

Mo/Mo

Dosimetry system used: MDH ELECTROMETER MODEL 1515 WITH MAMMO CHAMBER Energy correction factor: 0.99

Imaging mode: MANUAL

Image receptor: DIGITAL Size (cm): 18 by 23

Field restriction: 18X23

SID (cm): 66.0

Phantom: GAMMEX RMI MAMMO PHANTOM SER # 156-15217

Nominal kVp setting:	31	32	
Target/Filtration:	Mo/Mo	Mo/Mo	
~~AEC~~ density control setting:	MANUAL	MANUAL	
mA setting:	100	100	
Measured HVL (mm Al):	0.40	0.40	
(SECONDS) →	(0.515)	(0.426)	

Measured entrance exposure:	R	mAs	R	mAs	R	mAs
Exposure #1	0.692	50.0	0.606	40.0		
Exposure #2	0.692	50.0	0.606	40.0		
Exposure #3	0.692	50.0	0.606	40.0		
Exposure #4	0.692	50.0	0.606	40.0		
(mR/mAs) →	(13.8)		(15.2)			
Mean values	0.692	50.0	0.606	40.0		
Standard deviations (SD)	0.0	0.0	0.0	0.0		
Coefficients of variation (CV)	0.0	0.0	0.0	0.0		

Energy-corrected exposure:	0.685	0.600	
Dose conversion factor from Table 1-3 (mrad/R):	203	204	
Computed average glandular dose (mrad):	139.0	122.0	

Action Limit: If coefficient of variation for either R or mAs exceeds 0.05, seek service. If average glandular dose exceeds 300 mrads (3 mGy) for 4.2-cm effective breast thickness, seek service or technique adjustment.

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 [redacted] 7.9.97

8. Breast Entrance Exposure, Average Glandular Dose, and AEC Reproducibility

DIGITAL DMR

Mo/Rh

Dosimetry system used: MDH ELECTROMETER MODEL 1515 WITH MAMMO PROBE Energy correction factor: 0.99

Imaging mode: MANUAL

Image receptor: DIGITAL Size (cm): 18 by 23

Field restriction: 18X23

SID (cm): 66.0 cm

Phantom: GAMMEX RMI MAMMO PHANTOM SERIAL # 156-15217

Nominal kVp setting:	27	28	29
Target/Filtration:	Mo/Rh	Mo/Rh	Mo/Rh
AEC density control setting:	MANUAL	MANUAL	MANUAL
mA setting:	100	100	100
Measured HVL (mm Al):	0.42	0.43	0.43
(SECONDS) →	(0.972)	(0.747)	(0.644)

Measured entrance exposure:	R	mAs	R	mAs	R	mAs
Exposure #1	0.655	90.0	0.585	71.0	0.583	63.0
Exposure #2	0.655	90.0	0.585	71.0	0.583	63.0
Exposure #3	0.655	90.0	0.585	71.0	0.583	63.0
Exposure #4	0.655	90.0	0.585	71.0	0.583	63.0
(mR/mAs) →	(7.3)		(8.2)		(9.3)	
Mean values	0.655	90.0	0.585	71.0	0.583	63.0
Standard deviations (SD)	0.0	0.0	0.0	0.0	0.0	0.0
Coefficients of variation (CV)	0.0	0.0	0.0	0.0	0.0	0.0

Energy-corrected exposure:	0.648	0.579	0.577
Dose conversion factor from Table 1-3 (mrad/R):	212	217	218
Computed average glandular dose (mrad):	137.0	126.0	126.0

Action Limit: If coefficient of variation for either R or mAs exceeds 0.05, seek service. If average glandular dose exceeds 300 mrads (3 mGy) for 4.2-cm effective breast thickness, seek service or technique adjustment.

Appendix 3: Data Recording and Analysis Forms [redacted] 7.9.97

DIGITAL DMR

8. Breast Entrance Exposure, Average Glandular Dose, and AEC Reproducibility

Mo/Rh

Dosimetry system used: MDH ELECTROMETER MODEL 1515 WITH MAMMO PROBE Energy correction factor: 0.99

Imaging mode: MANUAL

Image receptor: DIGITAL Size (cm): 18 by 23

Field restriction: 18X23

SID (cm): 66.0 CM

Phantom: GAMMEX RMI mammo phantom SERIAL # 156-1527

Nominal kVp setting:	30	31	32
Target/Filtration:	Mo/Rh	Mo/Rh	Mo/Rh
AEC density control setting:	MANUAL	MANUAL	MANUAL
mA setting:	100	100	100
Measured HVL (mm Al):	0.44	0.44	0.45
(SECONDS) →	(0.497)	(0.463)	(0.426)

Measured entrance exposure:	R	mAs	R	mAs	R	mAs
Exposure #1	0.513	50.0	0.509	45.0	0.496	40.0
Exposure #2	0.513	50.0	0.509	45.0	0.496	40.0
Exposure #3	0.513	50.0	0.509	45.0	0.496	40.0
Exposure #4	0.513	50.0	0.509	45.0	0.496	40.0
(mR/mAs) →	(10.3)		(11.3)		(12.4)	
Mean values	0.513	50.0	0.509	45.0	0.496	40.0
Standard deviations (SD)	0.0	0.0	0.0	0.0	0.0	0.0
Coefficients of variation (CV)	0.0	0.0	0.0	0.0	0.0	0.0

Energy-corrected exposure:	0.508	0.504	0.491
Dose conversion factor from Table 1-3 (mrad/R):	222	223	227
Computed average glandular dose (mrad):	113.0	112.0	111.0

Action Limit: If coefficient of variation for either R or mAs exceeds 0.05, seek service. If average glandular dose exceeds 300 mrads (3 mGy) for 4.2-cm effective breast thickness, seek service or technique adjustment.

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Appendix 3: Data Recording and Analysis Forms ([redacted]) 7.9.97

8. Breast Entrance Exposure, Average Glandular Dose, and AEC Reproducibility

DIGITAL DMR

Rh | Rh

Dosimetry system used: MDH ELECTROMETER MODEL 1615 with MAMMO CHAMBER Energy correction factor: 0.99

Imaging mode: MANUAL

Image receptor: DIGITAL Size (cm): 18 by 23

Field restriction: 18x23

SID (cm): 160.0 CM

Phantom: GAMMEX RMI MAMMO PHANTON Ser. # 156-15217

Nominal kVp setting:	28		29		30	
Target/Filtration:	Rh | Rh		Rh | Rh		Rh | Rh	
~~AEC~~ density control setting:	MANUAL		MANUAL		MANUAL	
mA setting:	75		75		75	
Measured HVL (mm Al):	0.42		0.43		0.45	
(SECONDS) →	(0.786)		(0.615)		(0.480)	
Measured entrance exposure:	R	mAs	R	mAs	R	mAs
Exposure #1	0.497	56.0	0.446	45.0	0.394	36.0
Exposure #2	0.497	56.0	0.446	45.0	0.394	36.0
Exposure #3	0.497	56.0	0.446	45.0	0.394	36.0
Exposure #4	0.497	56.0	0.446	45.0	0.394	36.0
(mR/mAs) →	(8.9)		(9.9)		(10.9)	
Mean values	0.497	56.0	0.446	45.0	0.394	36.0
Standard deviations (SD)	0.0	0.0	0.0	0.0	0.0	0.0
Coefficients of variation (CV)	0.0	0.0	0.0	0.0	0.0	0.0
Energy-corrected exposure:	0.492		0.442		0.390	
Dose conversion factor from Table 1-3 (mrad/R):	224		230		241	
Computed average glandular dose (mrad):	110.0		102.0		94.0	

Action Limit: If coefficient of variation for either R or mAs exceeds 0.05, seek service. If average glandular dose exceeds 300 mrads (3 mGy) for 4.2-cm effective breast thickness, seek service or technique adjustment.

Appendix 3: Data Recording and Analysis Forms ([redacted] 7.9.97

8. Breast Entrance Exposure, Average Glandular Dose, and AEC Reproducibility

DIGITAL DMR

Rh/Rh

Dosimetry system used: MDH ELECTROMETER MODEL 1515 with MAMMO CHAMBER Energy correction factor: 0.99

Imaging mode: MANUAL

Image receptor: DIGITAL Size (cm): 18 by 23

Field restriction: 18 x 23

SID (cm): 66.0 CM

Phantom: GAMMEX RMI. MAMMO PHANTOM SER. # 156-15217

Nominal kVp setting:	31	32	
Target/Filtration:	Rh/Rh	Rh/Rh	
AEC density control setting:	MANUAL	MANUAL	
mA setting:	75	75	
Measured HVL (mm Al):	0.46	0.47	
(SECONDS) →	(0.439)	(0.398)	

Measured entrance exposure:	R	mAs	R	mAs	R	mAs
Exposure #1	0.387	32.0	0.371	28.0		
Exposure #2	0.387	32.0	0.371	28.0		
Exposure #3	0.387	32.0	0.371	28.0		
Exposure #4	0.387	32.0	0.371	28.0		
(mR/mAs) →	(12.1)		(13.3)			
Mean values	0.387	32.0	0.371	28.0		
Standard deviations (SD)	0.0	0.0	0.0	0.0		
Coefficients of variation (CV)	0.0	0.0	0.0	0.0		

Energy-corrected exposure:	0.383	0.367	
Dose conversion factor from Table 1-3 (mrad/R):	246	251	
Computed average glandular dose (mrad):	94.0	92.0	

Action Limit: If coefficient of variation for either R or mAs exceeds 0.05, seek service. If average glandular dose exceeds 300 mrads (3 mGy) for 4.2-cm effective breast thickness, seek service or technique adjustment.

Univ. of Massachusetts Med. Ctr.
Worcester, Mass. 01605

Digital Mammo Image Eval. 97

Digital Mammography Phantom Image Evaluation						
RMI Mammographic Phantom serial #156-15217				Date: 7/03/97		
(all performed with grid in)						
Target/Filter	**mAs**	**kVp**	**WW/WL settings**	**Fibers**	**Speck group**	**Masses**
Mo/Mo	110	27	574/506	6	3 (5/6)	4
Rh/Rh	56	28	279/97	4	3 (1/6)	3
Image Evaluation						
RMI Mammographic Phantom serial #156-15217				(all performed with grid in)		
Target/Filter	**mAs**	**kVp**	**WW/WL settings**	**Fibers**	**Speck group**	**Masses**
Mo/Mo	25	27	137/100	3	3 (2/6)	3
Mo/Mo	50	27	146/239	4	3	4
Mo/Mo	100	27	162/510	5	3 (3/6)	4
Mo/Mo	140	27	163/748	5	3 (5/6)	4
Mo/Mo	200	27	266/1088	5	4	4
Mo/Mo	250	27	281/1339	5	4 (1/6)	4
Target/Filter	**mAs**	**kVp**	**WW/WL settings**	**Fibers**	**Speck group**	**Masses**
Rh/Rh	25	28	207/4	2	2 (4/6)	2
Rh/Rh	50	28	205/70	4	3	3
Rh/Rh	100	28	211/228	5	3 (4/6)	4
Rh/Rh	140	28	216/346	5	3 (4/6)	4
Rh/Rh	200	28	217/521	6	3 (5/6)	4
Rh/Rh	250	28	148/488	5	4	4
***Note: This image was taken with approx. 1.0cm added acrylic to 4.5 cm mammo phantom**						
Target/Filter	**mAs**	**kVp**	**WW/WL settings**	**Fibers**	**Speck group**	**Masses**
Rh/Rh	125	28	178/141	4	3	3
*90.0 mAs is used on our other the DMR with film/screen at 27 kVp and Mo/Mo target filter						

meter setting (3p

Mo/Mo

4. kVp Accuracy/Reproducibility

kVp meter used: RMI mammographic kVp meter MODEL 232

Nominal kVp setting	25	26	27	28	29	30	31	32
Nominal focal spot size (mm)	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3
Exposure time								
mA (or mAs) setting	28.0	28.0	28.0	28.0	28.0	28.0	28.0	28.0
Measured kVp values								
kVp_1	24.1	25.3	26.4	27.6	28.9	30.1	31.4	32.6
kVp_2	24.1	25.3	26.4	27.6	28.9	30.1	31.4	32.6
kVp_3	24.1	25.3	26.4	27.6	28.9	30.1	31.4	32.6
kVp_4	24.1	25.3	26.4	27.6	28.9	30.1	31.4	32.6
Mean kVp <kVp>								
Standard dev. σ_{kVp}								
Additional kVp measurements (if needed)								
kVp_5								
kVp_6								
kVp_7								
kVp_8								
kVp_9								
kVp_{10}								
Recalculated:								
Mean kVp <kVp>	24.1	25.3	26.4	27.6	28.9	30.1	31.4	32.6
Standard dev. σ_{kVp} (using 10 readings)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<kVp> – Nominal kVp	-0.9	-0.7	-0.6	-0.4	-0.1	+0.1	+0.4	+0.6
0.05 x Nominal kVp	1.25	1.30	1.35	1.40	1.45	1.50	1.55	1.60
kVp coefficient of variation $\frac{\sigma_{kVp}}{<kVp>}$	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

Action Limit: If <kVp> differs from the nominal kVp by more than ±5% of the nominal kVp, or if the kVp coefficient of variation exceeds 0.02, then seek service correction.

Before calibration Digital ummc

Rh/Rh

Before calibration

4. kVp Accuracy/Reproducibility

kVp meter used: Tektronic x 2232 Digital Storage Oscilliscope (performed by G.E. service G. Keyter)

Nominal kVp setting	25	26	27	28	29	30	31	32	33	34	35
Nominal focal spot size (mm)	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3
Exposure time											
mA (or mAs) setting	28.0	28.0	28.0	28.0	28.0	28.0	28.0	28.0	28.0	28.0	28.0
Measured kVp values											
kVp_1	24.1	25.3	26.4	27.6	28.9	30.1	31.4	32.6			
kVp_2	24.1	25.3	26.4	27.6	28.9	30.1	31.4	32.6			
kVp_3	24.1	25.3	26.4	27.6	28.9	30.1	31.4	32.6			
kVp_4	24.1	25.3	26.4	27.6	28.9	30.1	31.4	32.6			
Mean kVp <kVp>											
Standard dev. σ_{kVp}											
Additional kVp measurements (if needed)											
kVp_5											
kVp_6											
kVp_7											
kVp_8											
kVp_9											
kVp_{10}											
Recalculated:											
Mean kVp <kVp>	24.1	25.3	26.4	27.6	28.9	30.1	31.4	32.6			
Standard dev. σ_{kVp} (using 10 readings)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0			
<kVp> – Nominal kVp	-0.9	-0.7	-0.6	-0.4	-0.1	+0.1	+0.4	+0.6			
0.05 x Nominal kVp	1.25	1.30	1.35	1.40	1.45	1.50	1.55	1.60			
kVp coefficient of variation $\frac{\sigma_{kVp}}{<kVp>}$											

Action Limit: If <kVp> differs from the nominal kVp by more than ±5% of the nominal kVp, or if the kVp coefficient of variation exceeds 0.02, then seek service correction.

University of Massachusetts
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University of Massachusetts Medical Center
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Worcester, MA 01655
(508) 856-2069
FAX: (508) 856-4669

Andrew Karellas, Ph.D.
Associate Professor of Radiology
Director, Radiologic Physics

September 29, 1997

R. Edward Hendrick, Ph.D.
Division of Radiological Sciences
Department of Radiology, C278
4200 East Ninth Avenue
Denver, CO 80262

Via Fax: (303) 315-8993

Dear Ed:

The following are the data you requested on the output of the digital and film DMR units which are located in our digital mammography room. All measurements were recorded with a calibrated MDH 1515 detector using a mammographic chamber. The chamber was placed at 4.5 cm above the breast holding platform and about 3 cm from the chest wall. The ACR phantom was used and the compression plate was above the phantom and detector. The exposure was recorded from 22 - 35 kVp for both film and digital units. All data are for Mo/Mo target filter combinations for both units. I will be happy to conduct additional measurements for other combinations if you wish.

We also recorded the exposure time in milliseconds for each exposure and calculated the mR/mAs. All exposures were taken at a fixed mAs setting of 100 mAs Figure 1 shows the measured exposure as a function of kVp. Please note that the power dependence of the exposure versus kVp is about 3.2 as shown in the curve fits in Figure 1. This is contrary to what we observed with standard well-filtered x-ray tubes which have typically a kVp power dependence of close to 2.0 - 2.1. Figure 2 shows the measured exposure time using the MDH 1515 in the pulse mode as a function of kVp. Note the increase in exposure time beyond 30 kVp in Figure 2; this must be caused by the automatic decrease in mA from 100 to approximately 80 kVp at settings >30 kVp. The date of all the above measurements was Sepember 17, 1997.

Please call me if you have any questions.

Sincerely,

Andrew Karellas, Ph.D.
Associate Professor of Radiology
Director, Radiologic Physics

AK/rl
Enclosure
!ak\misc\hendrick.003!

	kVp	Film mR	Film time(ms)	Film mR/mAs	Dig mR	Dig Time(ms)	Dig mR/mAs
0	22.000	454.00	1.2500	4.5000	425.00	1.2500	4.3000
1	23.000	540.00	1.2150	5.4000	505.00	1.2060	5.1000
2	24.000	634.00	1.1790	6.3000	594.00	1.1690	5.9000
3	25.000	738.00	1.1430	7.4000	689.00	1.1440	6.9000
4	26.000	843.00	1.1120	8.4000	789.00	1.1120	7.9000
5	27.000	958.00	1.0800	9.6000	898.00	1.0810	9.0000
6	28.000	1080.0	1.0530	10.800	1008.0	1.0520	10.100
7	29.000	1203.0	1.0270	12.000	1126.0	1.0250	11.300
8	30.000	1333.0	0.99000	13.300	1247.0	1.0000	12.500
9	31.000	1472.0	1.0350	14.700	1374.0	1.0320	13.700
10	32.000	1602.0	1.0680	16.000	1504.0	1.0660	15.000
11	33.000	1743.0	1.1020	17.400	1642.0	1.0950	16.400
12	34.000	1890.0	1.1350	18.900	1773.0	1.1300	17.700
13	35.000	2030.0	1.1700	20.300	1922.0	1.1620	19.200

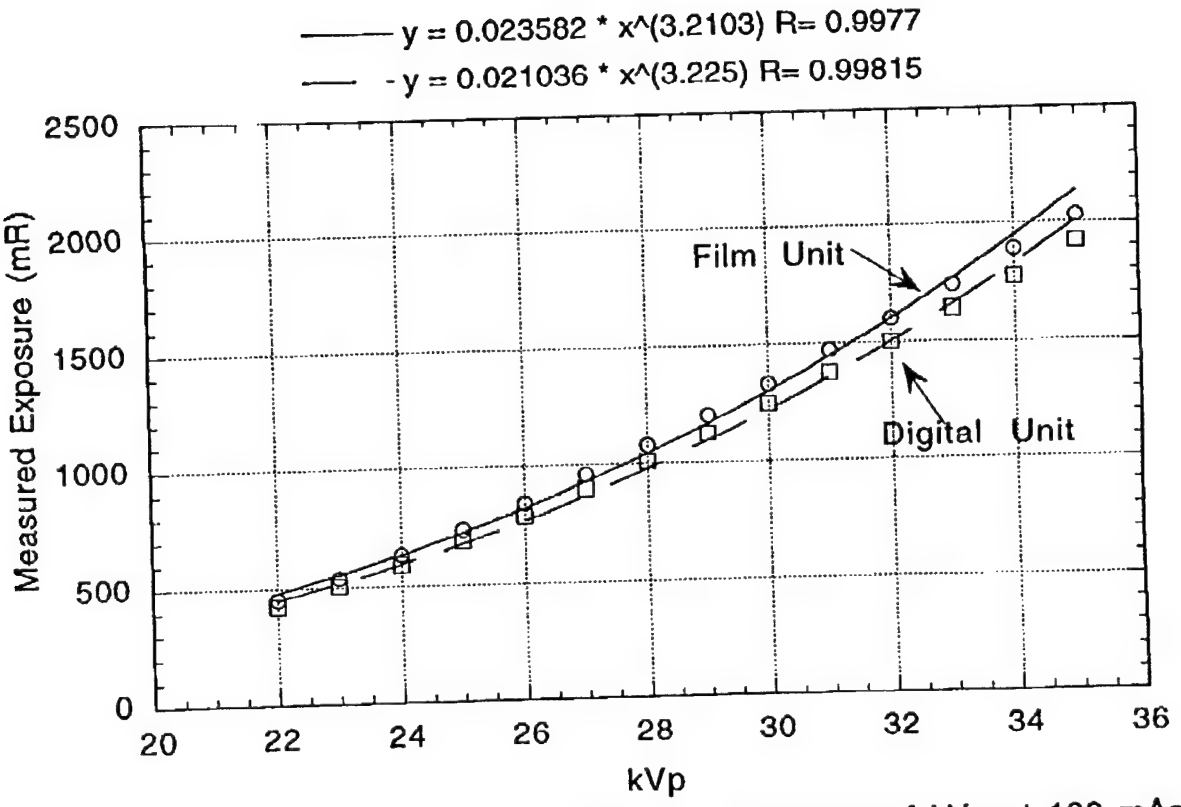


Figure 1. Measured Exposure as a function of kVp at 100 mAs

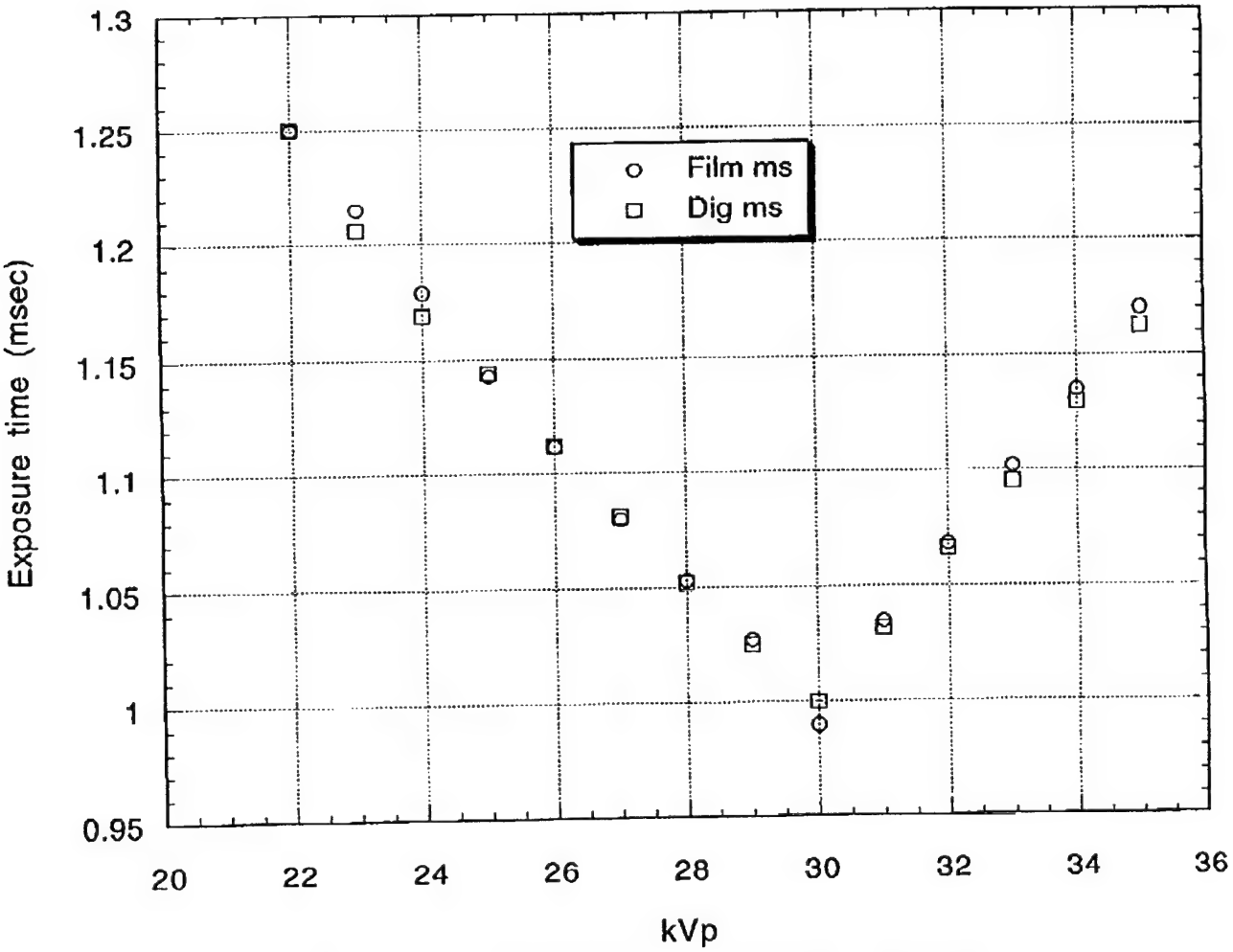


Figure 2. Measured exposure time vs kVp at 100 mAs.

Full Field Digital Mammography

Technologists Quality Control Minimum Test Frequencies

Test	Minimum Frequency
Phantom Image Acquisition	Daily
Nitrogen Tank Inspection	Daily
Water Tank Inspection	Daily
Hose and Cable Inspection	Daily
Shutdown & Reboot	Weekly
Calibrate	Weekly
Flat-Field Uniformity	Weekly
SNR	Weekly
Display Monitor Clean	Weekly
Viewing Conditions	Weekly
Unit Visual Checklist	Monthly
Compression	Quarterly
Repeat Analysis	Quarterly

Laser Printer Tests - if images are read from film.

Test	Minimum Frequency
SMPTE Test Pattern	Daily
Darkroom Cleanliness	Daily
Phantom Image	Weekly
Viewboxes and Viewing Conditions	Weekly
Darkroom Fog	Semi-annually
Analysis of Fixer Retention	Semi-annually

Daily QC Requirements For Full Field Digital Mammography

Facility: _____

kVp: _____

mAs: _____

Target / Filter _____

Room: _____

Month: _____

Year: _____

Date -->	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Day -->																															
Initials																															
Nitrogen Tank PSI																															
Water Tank Level																															
Water Tank Temp.																															
Hoses and Cabling Unobstructed																															
ACR Phantom Acquisition OK																															
Fibers																															
Speck Groups																															
Masses																															
Artifacts																															

Action Limit: Nitrogen Tank PSI: 500

Water Tank Temp: 30C +/- 2C

Remarks: _____

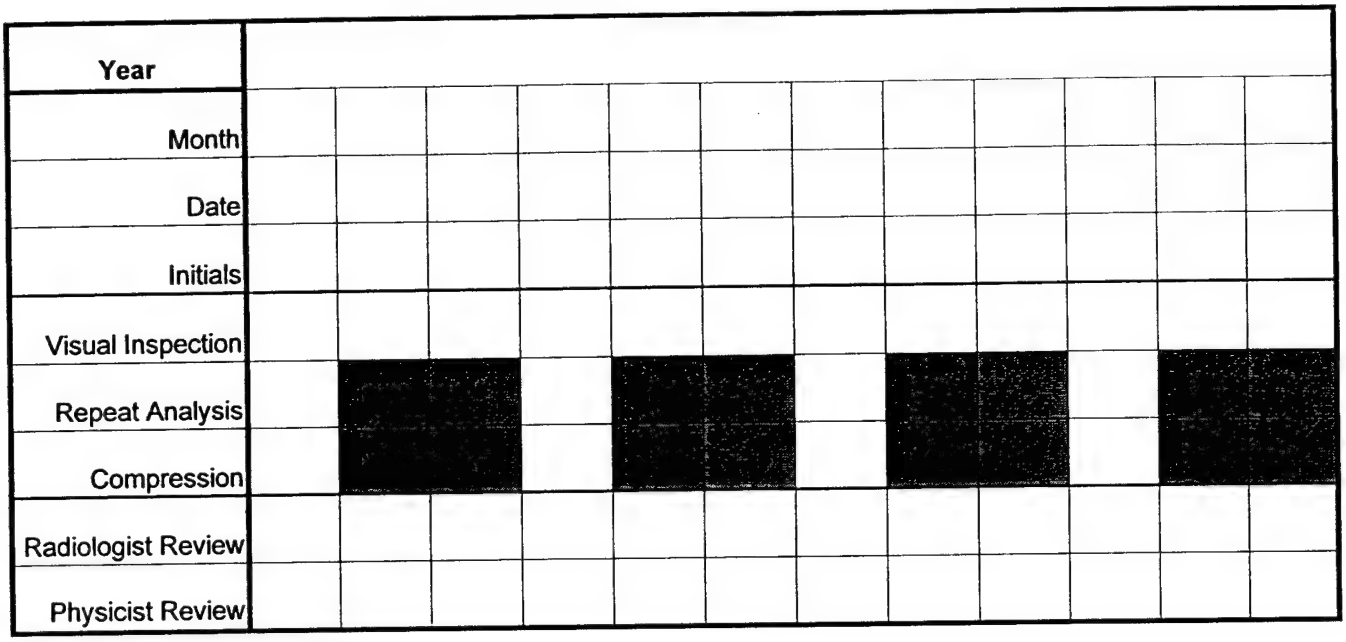
Weekly QC Requirements For Full Field Digital Mammography

Facility: _____ Room: _____

Year: _____ **Compression Paddle: Out For All Tests**

Date --->										
Day --->										
Initials										
Shutdown & Reboot										
Pre-Calibration Images										
1 inch acrylic, 25 kV, 50 mAs										
Patient ID										
100 um - Mo/Mo										
100 um - Mo/Rh										
100 um - Rh/Rh										
Calibration Files (Bad Pixel)										
100 um Bad Pixel (Grid Out)										
Number of Bad Pixels										
Clusters, Bad DL's, etc., All Zero? Y/N										
If not 0, description:										
Conversion Factor (Grid out)										
C.F. per incident X-ray										
Calibration Files (Gain Files)										
100 um - Mo/Mo (Grid In, 1 inch Ac.)										
100 um - Mo/Rh (1 inch Acrylic)										
100 um - Rh/Rh (2 inch Acrylic)										
MTF										
MTF at 2 lp/mm										
MTF at 5 lp/mm										
Post-Calibration Images										
1 inch acrylic, 25 kV, 50 mAs										
100 um - Mo/Mo										
100 um - Mo/Rh										
100 um - Rh/Rh										
Subtraction Completed										
100 um - Mo/Mo										
100 um - Mo/Rh										
100 um - Rh/Rh										
Subtraction Images OK										
100 um - Mo/Mo										
100 um - Mo/Rh										
100 um - Rh/Rh										
Flat Field Uniformity										
Bkgd Signal Mo/Mo										
Bkgd St. Dev. Mo/Mo										
SNR Mo/Mo										
Bkgd Signal Mo/Rh										
Bkgd St. Dev. Mo/Rh										
SNR Mo/Rh										
Bkgd Signal Rh/Rh										
Bkgd St. Dev. Rh/Rh										
SNR Rh/Rh										
Display Monitor Clean										

Monthly and Quarterly QC for Full Field Digital Mammography



Full Field Digital Mammography QC Visual Checklist

Frequency: Monthly

Room: _____ Unit: _____

	Year												
	Month												
	Date												
	Initials												
C-ARM	SID indicator or marks												
	Angulation indicator												
	Locks (all)												
	Field light												
	Smoothness of motion												
	Inspect all paddles for cracks												
CONTROL BOOTH	Panel switches/lights/meters												
	Technique charts												
OTHER	Cleaning solution												

Pass: P
Fail: F
Does Not Apply: NA

Full Field Digital Mammography Medical Physicists Tests

	Test	Frequency
1	Conversion Factor	Monthly
2	MTF	Monthly
3	Image Quality - ACR Phantom	Quarterly
4	Image Quality - SMPTE Pattern	Quarterly
5	Unit Assembly Evaluation	Yearly
6	Collimation Assessment	Yearly
7	Evaluation Of Focal Spot	Yearly
8	Sytem Limiting Resolution	Yearly
9	kVp Accuracy/Reproducibility	Yearly
10	Beam Quality (HVL)	Yearly
11	Breast Entrance Exposure	Yearly
12	Artifact Evaluation/Flat Field Uniformity	Yearly
13	Detector Signal to Noise Ratio Measurement	Yearly
14	Geometric Distortion, Resolution Uniformity	Yearly
15	Detector Contrast Function	Yearly

	Laser Printer - If Applicable	Frequency
1	Image Quality - ACR Phantom	Yearly
2	Image Quality - SMPTE Pattern	Yearly
3	Artifact Evaluation/Flat Field Uniformity	Yearly
4	System Limiting Resolution	Yearly

1. Conversion Factor

Grid: Out

kVp: _____

mAs: _____

Target/Filter: Rh/Rh

Conversion Factor Per Incident X-ray: [ ]

Action Limit: C.F. must be greater than 110.

2. MTF

1st two images: No bar.

3rd image: With Bar.

MTF lp/mm	MTF
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	

3. Image Quality Evaluation - ACR Phantom

Phantom Used: _____

	Previous Image	Current Image
kVp setting		
Target/Filter		
mAs		
Number of fibers seen		
Fiber change		
Number of speck groups seen		
Speck group change		
Number of masses seen		
Mass change		

Action Limit:

If fiber, speck group, or mass score changes, the scource of change should be identified and corrected.

4. Image Quality Evaluation - SMPTE test pattern

	Previous Image	Current Image
All steps of SMPTE discernible?		
Low contrast targets of SMPTE discernible?		
Luminance:		

Action Limit:

If the SMPTE test pattern and low contrast targets are not discernible, the scource of change should be identified and corrected.

Full Field Digital Mammography Equipment Evaluation

Site: _____ Date: _____

_____

Equipment

X-Ray Unit Manufacturer _____ Model _____

Laser Printer Manufacturer _____ Model _____

Clinical Technique Chart

Breast Thickness	Exposure Mode	kVp Setting	mAs Setting	Target/Filter Combination	I.R. Size	Grid Used
2 cm	Manual				18 x 24	Yes
4 cm	Manual				18 x 24	Yes
6 cm	Manual				18 x 24	Yes
8 cm	Manual				18 x 24	Yes

5. Full Field Digital Mammographic Unit Assembly Evaluation

Free standing unit is mechanically stable.	Y	N
All moving parts move smoothly, without obstructions to motion.	Y	N
All locks and detents work properly.	Y	N
Image receptor is free from vibrations during exposure.	Y	N
Compressed breast thickness scale is accurate to +/- 0.5 cm, reproducible to +/- 0.2 cm.	Y	N
Patient or operator is not exposed to sharp or rough edges or other hazards.	Y	N
Operator technique charts are posted.	Y	N
Operator protected during exposure by adequate radiation shielding.	Y	N
Nitrogen tank, water bath, and hoses are securely fastened and safely placed.	Y	N
Water bath temperature is stable and correct (30C +/- 1C).	Y	N

Other: _____

6. Collimation Assessment

Source to Image Receptor Distance (SID): _____

Deviation between X-ray field and light field:

Collimator			
Left Edge: Deviation			
Right Edge Deviation			
Sum of magnitudes of left and right edge deviations			
Sum as % if SID			
Anterior Ed Deviation			
Chest Edg Deviation			
Sum of magnitudes of left and right edge deviations			
Sum as % if SID			

Action Limit: If sum of left plus right deviations or anterior plus chest edge deviations exceeds 2% of the SID, seek service adjustment.

X-ray field within image receptor left, right, anterior: Y N

Difference between X-ray field and image receptor at chest wall:

Collimator			
Difference between X-ray image receptor at chest			
Difference as % of SID			

Action Limit: If X-ray field extends beyond the image receptor (left, right, or anterior) or if X-ray field extends beyond the chest wall edge of image receptor by more than 2% of SID, seek service adjustment.

Alignment of chest wall edges of compression paddle and image receptor:

Collimator			
Difference between compression paddle edge and image receptor at chest wall			
Difference as % of SID			

Action Limit: If chest wall edge of compression paddle is within the image receptor or projects beyond the chest wall edge of the image receptor by more than 1% of SID, seek service correction.

7. Evaluation of Focal Spot Measurement

High Contrast resolution pattern measurement of limiting resolution

Nominal Focal Spot Size, f_{nom}				
Nominal kVp setting				
Nominal mA setting				
mAs				
Magnification Factor		Contact		
Limiting	bars parallel to A-C axis			
Resolution	bars perpendicular to A-C axis			

Action Limit:

If the limiting resolution is <13 line-pairs per mm with the bars parallel to the anode-cathode axis or is <11 line-pairs per mm with the bars perpendicular to the anode-cathode axis, then a more detailed investigation of the reason should be made using a slit camera.

8. System Limiting Resolution

Resolution Test Tool: _____

	Large	Small		
Focal Spot Size				
kVp				
mAs				
mA				
lp/mm				

Action Limit:

If the limiting resolution is <0.45/p lp/mm, then more detailed investigation of the reason should be made.

9. kVp Accuracy/Reproducibility

kVp meter used: _____

Nominal kVp setting							
Nominal focal spot size							
Exposure time							
mA (or mAs) setting							
Measured Values kVp 1							
kVp 2							
kVp 3							
kVp 4							
Mean kVp							
Standard Deviation							
Mean kVp - Nominal kVp							
0.05 x Nominal kVp							
kVp coefficient of variation (Std. dev. / mean kVp)							

Action Limit:

If mean kVp differs from the nominal by more than +/-5% of the nominal kVp, or if the kVp coefficient of variation exceeds 0.02, then seek service adjustment.

10. Beam Quality (HVL) Measurement

Dosimetry system used: _____

Nominal kVp setting							
Nominal focal spot size							
Target/Filter							
mAs setting							
No Aluminum Filtration, E_o							
0.2 mm of added Aluminum, E_2							
0.3 mm of added Aluminum, E_3							
0.4 mm of added Aluminum, E_4							
0.5 mm of added Aluminum, E_5							
0.6 mm of added Aluminum, E_6							

Record thickness and exposures that bracket $E_o/2$

ta < tb	ta							
	tb							
Ea > Eb	Ea							
	Eb							
	Calculated HVL							

Calculated HVL = (tb ln(2Ea/Eo) - ta ln(2Eb/Eo)) / ln(Ea/Eb)

Action Limit: If measured HVL < kVp/100 +0.03mm (in mm Al)

or

If measured HVL > kVp/100 + C (in mm Al)

Where C= 0.12 for Mo/Mo
0.19 for Mo/Rh
0.22 for Rh/Rh

then seek service.

11. Breast Entrance Exposure, Average Glandular Dose, and Reproducibility

Dosimetry system used: _____
Imaging receptor size: _____
Field restriction: _____
SID (cm) _____
Phantom ID: _____

Phantom type and thickness	4.2 cm ACR	2 cm	4 cm	6 cm	8 cm
Nominal kVp setting					
Target/Filter					
mAs setting					
Measured HVL (mm Al)					

Measured Entrance Exposure	R	R	R	R	R
Exposure #1					
Exposure #2					
Exposure #3					
Exposure #4					

Mean Values					
Standard Deviations (SD					
Coefficients of variation (CV)					

Energy Corrected Exposure:					
Dose Conversion Factor (mrad/R)					
Computed Average Glandular Dose **(mrad)**					

Action Limit:

If coefficient of variation for either R or mAs exceeds 0.05, seek service. If average glandular dose exceeds 300 mrads (3 mGy) for a 4.2-cm effective breast thickness, seek service or technique adjustment.

12. Artifact Evaluation/Flat Field Uniformity

Type of Attenuator _____

Thickness of Attenuator _____

kVp Setting _____

mAs Setting _____

Focal Spot Size _____

Image Receptor Size _____

	Mo/Mo		Mo/Rh		Rh/Rh	
	CRT	Detector	CRT	Detector	CRT	Detector
Artifact Visible?						
Equipment Artifact?						
Detector?						
Grid?						
Phantom Defect?						
Other						
Low Frequency Uniformity						

Description of Artifacts: _____

_____

_____

_____

If significant artifacts are visible, contact the appropriate person maintaining or servicing the digital mammography equipment.

13. Detector Signal To Noise Ratio Measurement

Type of Attenuator _____

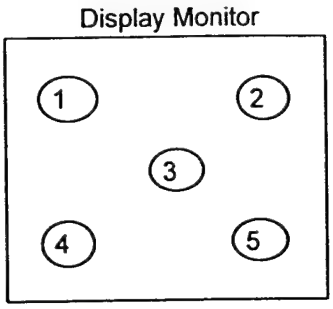
Thickness of Attenuator _____

kVp Setting _____

mAs Setting _____

Focal Spot Size _____

Image Receptor Size _____



Background Signal and Std. Dev.	Mo/Mo		Mo/Rh		Rh/Rh	
	Previous	Current	Previous	Current	Previous	Current
Location 1 Signal						
Location 1 Standard Deviation						
Location 1 SNR						
SNR Change (Number & %)		%		%		%
Location 2 Signal						
Location 2 Standard Deviation						
Location 2 SNR						
SNR Change (Number & %)		%		%		%
Location 3 Signal						
Location 3 Standard Deviation						
Location 3 SNR						
SNR Change (Number & %)		%		%		%
Location 4 Signal						
Location 4 Standard Deviation						
Location 4 SNR						
SNR Change (Number & %)		%		%		%
Location 5 Signal						
Location 5 Standard Deviation						
Location 5 SNR						
SNR Change (Number & %)		%		%		%
Object Signal						
Object Standard Deviation						
Object SNR						
SNR Change (Number & %)		%		%		%

Action Limit: If signal change exceeds +/-8% or object change exceeds +/-10% the source of change should be identified

14. Detector Dynamic Range

Phantom Material: _____

Thickness	kVp	mAs	T/F	Bkgd Signal	Bkgd Std. Dev	Bkgd SNR	Object Signal	Object Std. Dev	Object SNR
2 cm									
4 cm									
4.2 cm									
6 cm									
8 cm									

Action Limit:

14. Geometric Distortion, Resolution Uniformity

Screen mesh used: _____

kVp setting: _____

mAs _____

Grid? _____

	Mo/Mo	Mo/Rh	Rh/Rh
Uniform Resolution over image area?			
Pattern not distorted?			

Description of distortion: _____

_____

_____

_____

_____

_____

Action Limit:

15. Detector Contrast Function

16. Laser Printer - If Available

1. Image Quality - SMPTE Test Pattern

	Previous Imag	Current Image
kVp setting		
mAs		
All steps of SMPTE discernible?		
Low contrast targets of SMPTE discernible?		
OD Position 1		
OD Position 2		
OD Position 3		
OD Position 4		
OD Position 5		
OD Position 6		
OD Position 7		
OD Position 8		
OD Position 9		
OD Position 10		
OD Low Contrast Targets		

Action Limit:
If the SMPTE test pattern and low contrast targets are not discernible, the source of change should be identified and corrected.

2. Image Quality - ACR Phantom

	Previous Imag	urrent Image
kVp setting		
Target/Filter		
mAs		
Number of fibers:		
Fiber change		
Number of speck groups:		
Speck group change		
Number of masses:		
Mass change		

Phantom: _____

Action Limit:

If fiber, speck group, or mass score changes, the source of change should be identified and corrected.

3. Artifact Evaluation / Flat Field Uniformity Evaluation

Type of Attenuator _____
Thickness of Attenuator _____
kVp Setting _____
mAs Setting _____
Focal Spot Size _____

OD	Mo/Mo	Mo/Rh	Rh/Rh
Artifact Visible?			
Equipment Artifact?			
Grid?			
Phantom Defect?			
Other			

If significant artifacts are visible, contact the appropriate person maintaining or servicing the processor or X-ray equipment.

4. System Limiting Resolution

Resolution Test Tool:

	Large	Small			
Focal Spot Size					
kVp					
mAs					
mA					
lp/mm					

If the limiting resolution is <0.45/p lp/mm, then more detailed investigation of the reason should be made.